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EDAN

M3A

Vital Signs Monitor

Version 1.7



About this Manual

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Statement

This manual will help you understand the operation and maintenance of the product better. It is reminded that the product shall be used strictly complying with this manual. User's operation failing to comply with this manual may result in malfunction or accident for which EDAN INSTRUMENTS, INC. (hereinafter called EDAN) can not be held liable.

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EDAN only considers itself responsible for any effect on safety, reliability and performance of the equipment if:

Assembly operations, extensions, re-adjustments, modifications or repairs are carried out by persons authorized by EDAN, and

The electrical installation of the relevant room complies with national standards, and

The instrument is used in accordance with the instructions for use.

Upon request, EDAN may provide, with compensation, necessary circuit diagrams, and other information to help qualified technician to maintain and repair some parts, which EDAN may define as user serviceable.

Terms Used in this Manual

This guide is designed to give key concepts on safety precautions.

WARNING

A **WARNING** label advises against certain actions or situations that could result in personal injury or death.

CAUTION

A **CAUTION** label advises against actions or situations that could damage equipment, produce inaccurate data, or invalidate a procedure.

NOTE

A **NOTE** provides useful information regarding a function or a procedure.

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Chapter 1 Intended Use and Safety Guidance

1.1 Intended Use/Indications for Use

This monitor is intended to be used for monitoring, storing, reviewing, recording, and generating alarms for SpO₂ (oxygen saturation of arterial blood), NIBP (non-invasive blood pressure) and TEMP (quick temperature or infrared ear temperature) of adults, pediatrics and neonates in hospital environments.

This monitor is used to monitor vital signals for patients and is suitable for use in hospital environments including out-patient department, wards and NICU.

Monitored parameters include: NIBP, SpO₂, pulse rate, Quick TEMP/Infrared TEMP.

1.2 Safety Guidance

1.2.1 Environment

Follow the instructions below to ensure completely safe electrical installation. The environment where the monitor will be used should be reasonably free from vibration, dust, corrosive or explosive gases, extremes of temperature, humidity, and so on. For a cabinet mounted installation, allow sufficient room at the front for operation and sufficient room at the rear for servicing with the cabinet access door open.

The monitor operates within specifications at ambient temperatures between 0 °C and +40 °C. Ambient temperatures that exceed these limits could affect the accuracy of the instrument and cause damage to the modules and circuits. Allow at least 2 inches (5 cm) clearance around the instrument for proper air circulation.

1.2.2 Power Source Requirements

Refer to *Appendix I*.

1.2.3 Grounding the Monitor

To protect the patient and hospital personnel, the cabinet of the monitor must be grounded. Accordingly, the monitor is equipped with a 3-wire cable which grounds the instrument to the power line ground (protective earth) when plugged into an appropriate 3-wire receptacle. If a 3-wire receptacle is not available, consult the hospital electrician.

Connect the grounding wire to the equipotential grounding terminal on the mains system. If it is not evident from the instrument specifications whether a particular instrument combination is hazardous or not, for example due to summation of leakage currents, the user should consult the manufacturers concerned or an expert in the field, to ensure that the necessary safety of all instruments concerned will not be impaired by the proposed combination.

1.2.4 Equipotential Grounding

Protection class 1 instruments are already included in the protective grounding (protective earth) system of the room by way of grounding contacts in the power plug. For internal examinations on the heart or the brain, the Monitor must have a separate connection to the equipotential grounding system. One end of the equipotential grounding cable (potential equalization conductor) is connected to the equipotential grounding terminal on the rear panel of the instrument and the other end to one point of the equipotential grounding system. The equipotential grounding system assumes the safety function of the protective grounding conductor if ever there is a break in the protective grounding system. Examinations in or on the heart (or brain) should only be carried out in medically used rooms incorporating an equipotential grounding system. Check each time before use that the instrument is in perfect working order. The cable connecting the patient to the instrument must be free of electrolyte.

WARNING

If the protective grounding (protective earth) system is doubtful, the monitor must be supplied by internal power only.

1.2.5 Condensation

Make sure that during operation, the instrument is free of condensation. Condensation can form when equipment is moved from one building to another, thus being exposed to moisture and differences in temperature.

1.2.6 Safety Precautions

WARNING and **CAUTION** messages must be observed. To avoid the possibility of injury, observe the following precautions during the operation of the instrument.

WARNING

- 1 If liquid is inadvertently splashed on the equipment or its accessories, it may enter the conduit or inside the monitor. At this moment, contact local Customer Service Center.
 - 2 The monitor is intended to be used by qualified physicians or personnel professionally trained. And they should be familiar with the contents of this user manual before operation.
 - 3 Only qualified service personnel can install this equipment. And only service personnel authorized by EDAN can open the shell.
 - 4 **EXPLOSION HAZARD**-Do not use the monitor in a flammable atmosphere where anesthetics or other flammable materials may accumulate.
 - 5 Do not attempt to connect or disconnect a power cord with wet hands. Make certain that your hands are clean and dry before touching a power cord.
-
-

WARNING

- 6 **SHOCK HAZARD-** the power receptacle must be a three-wire grounded outlet. A hospital grade outlet is required. Never adapt the three-prong plug of the monitor to fit a two-slot outlet.
 - 7 Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC/EN standards. Furthermore all configurations shall comply with the valid version of the system standard IEC/EN60601-1. Everybody who connects additional equipment to the signal input connector or signal output connector configures a medical system, and is therefore responsible that the system complies with the requirements of the valid version of the system standard IEC/EN60601-1. If in doubt, consult our technical service department or your local distributor.
 - 8 Use the battery only in this monitor. Do not connect battery directly to an electric outlet or cigarette lighter charger.
 - 9 Do not unplug the battery when monitoring.
 - 10 Make sure the monitor is used in the appointed range of voltage, the effect of power supply can be ignored.
 - 11 Do not solder the leading wire and the battery terminal directly.
 - 12 If liquid leaking from the battery gets into your eyes, onto your skin or clothes, do not rub your eyes. Wash them well with clean water and go to see a doctor immediately.
 - 13 Always keep the battery away from fire.
 - 14 Stop using the battery if abnormal heat, odor, discoloration, deformation or abnormal condition is detected during use, charge, or storage. Keep it away from the monitor.
 - 15 Do not use a battery with serious scar or deformation.
 - 16 Only patient cable and other accessories supplied by EDAN can be used. Or else, the performance and electric shock protection can not be guaranteed, and the patient may be injured.
 - 17 Please set the alarm according to the individual condition of patient to avoid delaying treatment. Ensure there will be an alarm audio prompt when an alarm occurs.
 - 18 Devices connecting with the monitor should be equipotential.
 - 19 When the monitor and electrosurgical device are used together, the user (physician or nurse) should guarantee the safety of patient.
 - 20 Please disinfect timely to prevent cross infection between patients.
 - 21 This monitor is not a device for treatment purposes.
-
-

WARNING

- 22 The simultaneous use of cardiac pacemaker and other patient-connected equipment may cause safety hazard.
 - 23 Only NIBP and SpO₂ applied parts of the monitor are defibrillation-proof. When a defibrillator is applied, keep other accessories away from the patient. Otherwise, it may result in damaging the monitor or harming the patient.
 - 24 Do not touch the patient, bed or instrument during defibrillation.
 - 25 During monitoring, if the power supply is off and there is no battery for standby, the monitor will be off, and only the patient information and alarm settings can be saved. After reconnecting the power supply, the user should turn on the monitor for monitoring.
 - 26 The equipment can provide protective means to prevent the patient from being burned when used with HF SURGICAL EQUIPMENT. The equipment can protect against the effects of the discharge of a defibrillator. Use only EDAN-approved accessories.
 - 27 The appliance coupler or mains plug is used as isolation means from supply mains. Position the monitor in a location where the operator can easily access the disconnection device.
 - 28 Do not service or maintain the monitor or any accessory which is in use with the patient.
 - 29 Without any external memory, all data measured (including trend data, review data, alarm events and so on) are cleared either when the monitor is turned off or when the monitor is powered down in the process of monitoring.
 - 30 Additional multiple socket-outlet or extension cord can't be connected to the system.
 - 31 Only items that have been specified as part of the system or specified as being compatible with the system can be connected to the system.
 - 32 SHOCK HAZARD - Don't connect electrical equipment, which has been supplied as a part of the system, directly to the wall outlet when the non-medical equipment is intended to be supplied by a multiple portable socket-outlet with an isolation transformer.
 - 33 SHOCK HAZARD - Don't connect electrical equipment, which has not been supplied as a part of the system, to the multiple portable socket-outlet supplying the system.
 - 34 Do not touch accessible parts of electrical equipment in the patient environment and the patient simultaneously.
-
-

WARNING

- 35 Connecting any accessory (such as external printer) or other device (such as the computer) to this monitor makes a medical system. In that case, additional safety measures should be taken during installation of the system, and the system shall provide:
- a) Within the patient environment, a level of safety comparable to that provided by medical electrical equipment complying with IEC/EN 60601-1, and
 - b) Outside the patient environment, the level of safety appropriate for non-medical electrical equipment complying with other IEC or ISO safety standards.
- 36 All the accessories connected to system must be installed outside the patient vicinity, if they do not meet the requirement of IEC/EN 60601-1.
- 37 Using accessories other than those specified may result in increased electromagnetic emission or decreased electromagnetic immunity of the monitoring equipment.
- 38 The monitor should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, you must check that normal operation is possible in the necessary configuration before you start monitoring patients.
- 39 Portable and mobile radio frequency (RF) communications equipment can affect medical electrical equipment, please refer to the recommended separation distances provided in Appendix A2 EMC Information.
- 40 The medical electrical equipment needs to be installed and put into service according to the EMC Information provided in this user manual.
- 41 Setting alarm limits to extreme values may cause the alarm system to become ineffective. It is recommended to use the default settings.
- 42 The monitors are intended for use by trained healthcare professionals in hospital environments.
- 43 Operation of the equipment exceeding the measurement range may cause inaccurate results.
- 44 High level interference may affect the normal functions of the equipment.
-
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CAUTION

- 1 **Electromagnetic Interference** – Ensure the environment in which the monitor is installed is not subject to any sources of strong electromagnetic interference, such as radio transmitters, mobile telephones, etc.
 - 2 Federal law (U.S.) restricts this device to sale by or on the order of a physician.
-
-

CAUTION

- 3 Keep the environment clean. Avoid vibration. Keep it far from corrosive medicine, dust area, high-temperature and humid environment.
 - 4 Remove a battery whose life cycle has expired from the monitor immediately.
 - 5 The monitor is designed for continuous operation and is “ordinary” (i.e. not drip or splash-proof).
 - 6 The device and accessories are to be disposed of according to local regulations after their useful lives. Alternatively, they can be returned to the dealer or the manufacturer for recycling or proper disposal. Batteries are hazardous waste. Do not dispose them together with house-hold garbage. At the end of their life hand the batteries over to the applicable collection points for the recycling of waste batteries. For more detailed information about recycling of this product or battery, please contact your local Civic Office, or the shop where you purchased the product.
 - 7 Do not immerse transducers in liquid. When using solutions, use sterile wipes to avoid pouring fluids directly on the transducer.
 - 8 Before use, the equipment, patient cable and sensor should be checked. Replacement should be taken if there is any evident defectiveness or aging symptom which may impair the safety or performance.
 - 9 Disposable devices are intended for single use only. They should not be reused as performance could degrade or contamination could occur.
 - 10 Avoid liquid splash and excessive temperature. The working temperature must be kept between 0 °C and +40 °C, and it is recommended to be kept between +10 °C and +40 °C when the monitor is equipped with TEMP module. The temperature should be kept between -20 °C and +55 °C during transportation and storage, and it is recommended to be kept between -20 °C and +50 °C when the monitor is equipped with TH module.
 - 11 If the monitor gets damp, put it in dry circumstance to dry it until it can work normally. If liquid pours on the monitor, please contact the service personnel authorized by EDAN.
 - 12 A potential hazard may exist if different alarm presets are used for the same or similar equipment in any single area.
 - 13 Assembly of the monitor and modifications during actual service life shall be evaluated based on the requirements of IEC60601-1.
-
-

NOTE:

- 1 Position the device in a location where the operator can easily see the screen and access the operating controls.

- 2 The monitor can only be used on one patient at a time.
- 3 The equipment is calibrated to display functional oxygen saturation.
- 4 This equipment is not intended for family usage.
- 5 If the device is discolored or damaged, then discontinue use of the device.
- 6 The pictures and interfaces in this manual are for reference only.
- 7 Regular preventive maintenance should be carried out every two years. You are responsible for any requirements specific to your country.
- 8 The materials with which the patient or any other person can come into contact conform with the standard of EN ISO 10993-1: 2009.

1.2.7 Explanation of Symbols on the Monitor

1		DEFIBRILLATION-PROOF TYPE BF APPLIED PART
2		TYPE BF APPLIED PART
3		TYPE CF APPLIED PART
4		Warning (Background: yellow; Symbol and outline: black)
5		Operating instructions
6		Refer to User Manual (Background: blue; Symbol: white)
7	P/N	Part Number
8		Equipotential grounding

9		Power Supply switch
10		RS-232 port
11		SERIAL NUMBER
12		CE marking
13		AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
14		Date of manufacture
15		MANUFACTURER
16		General symbol for recovery/recyclable
17		Disposal method
18	Rx Only	Caution: Federal law (U.S.) restricts this device to sale by or on the order of a physician.
19	IPX1	Ingress Protection IPX1 (Protected against vertically falling water drops)
20		(This mark is optional.) With respect to electrical shock, fire and mechanical hazards only in accordance with UL 60601-1 and CAN/CSA C22.2 No. 601.1
21		Caution

NOTE:

The user manual is printed in black and white.

Chapter 2 Installation of Monitor

NOTE:

To ensure that the monitor works properly, please read *Chapter 1 Intended Use and Safety Guidance*, and follow the steps before using the monitor.

2.1 Opening the Package and Checking

Visually examine the package prior to unpacking. If any signs of mishandling or damage are detected, contact the carrier to claim for damage. Open the package and take out the monitor and accessories carefully. Keep the package for possible future transportation or storage. Check the components according to the packing list.

- Check for any mechanical damage.
- Check all the cables, modules and accessories.

If there is any problem, contact the manufacturer or local representative immediately.

2.2 Connecting the Power Cable

Connection procedure of the AC power line:

- Make sure the AC power supply complies with the following specification: 100 V-240 V ~, 50 Hz/60 Hz.
- Apply the power line provided with the monitor. Plug the power line to input interface of the monitor. Connect the other end of the power line to a grounded power output.

NOTE:

Connect the power line to the jack special for hospital usage.

- Connect to the ground line if necessary. Refer to section *1.2 Safety Guidance* for details.

NOTE:

When the battery is provided, after the monitor is transported or stored, the battery must be recharged. Switching on AC power supply can recharge the battery no matter if the monitor is powered on.

2.3 Powering on the Monitor

Press the **ON/OFF** button on the front panel to power on the monitor, all the seven-segment displays are bright, and LOGO information is displayed on the screen.

WARNING

Do not use it on any patient if any sign of damage is detected, or the monitor displays some error messages. Contact biomedical engineer in the hospital or Customer Service Center immediately.

NOTE:

- 1 During POST, make sure all the seven segments are bright, which indicates the seven segments function well.
- 2 Check all the functions of the monitor and make sure that the monitor is in good condition.
- 3 If rechargeable batteries are provided, recharge them after using the monitor every time to ensure the electric power is enough.
- 4 The interval between double presses of the **ON/OFF** button should be more than 1 second.

2.4 Connecting Sensor to Patient

Connect all the necessary patient sensors between the monitor and the patient.

NOTE:

For information on correct connection, refer to related chapters.

Chapter 3 Introduction

3.1 General Information

The monitor integrates the function of parameter measurement modules, display and output to compose a compact, portable device. Its built-in replaceable battery provides convenience for patient movement.

You may frequently use the following functions:

- SpO₂ monitoring (Refer to Chapter *Monitoring SpO₂* for details)
- TEMP monitoring (Refer to Chapter *Monitoring TEMP* for details)
- NIBP monitoring (Refer to Chapter *Monitoring NIBP* for details)
- Alarm (Refer to Chapter *Alarms* for details)

The monitor is a user-friendly device with operations conducted by a few buttons on the front panel. Refer to section 3.3 *Button Functions* for more details.



M3A with the T2 TEMP module



M3A with the TH TEMP module



M3A with the F3000 TEMP module

Figure 3-1 M3A Vital Signs Monitor

M3A Vital Signs Monitor can monitor:

- SpO₂: Oxygen saturation of arterial blood (SpO₂);
 - Pulse Rate (PR);
 - SpO₂ PLETH (Plethysmogram);
- NIBP: Systolic Pressure (SYS);
 - Diastolic Pressure (DIA);
 - Mean Pressure (MAP);
 - Pulse Rate (PR).
- TEMP: Temperature.

3.2 Screen Display

The monitor is equipped with LCD. The patient parameters, waveforms, alarm messages, patient ID, time, monitor status and other information can be reflected from the screen.

If the monitor has SpO₂, NIBP and TEMP functions. As an option, the monitor can be configured to single SpO₂, single NIBP, NIBP+SpO₂, NIBP+TEMP or NIBP+SpO₂+TEMP.

The configuration is preset by the manufacturer, and it can not be changed by the user.

3.2.1 All Parameters Display

The screen is divided into three areas:

- 1 Parameter area ①
- 2 Waveform/ NIBP Multi-Group Review/ Trend list/ Trend Graph ②
- 3 Information area ③ ④

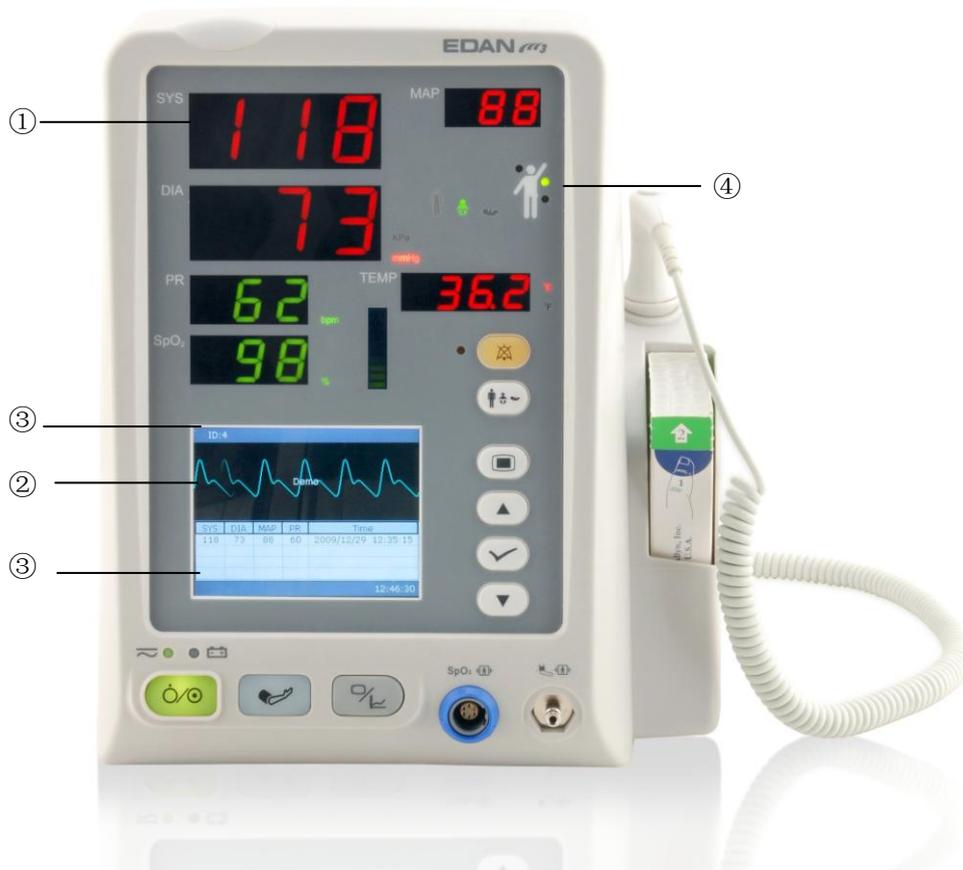


Figure 3-2 Main display

The NIBP multi-group Review and SpO₂ waveform area is displayed as follows:

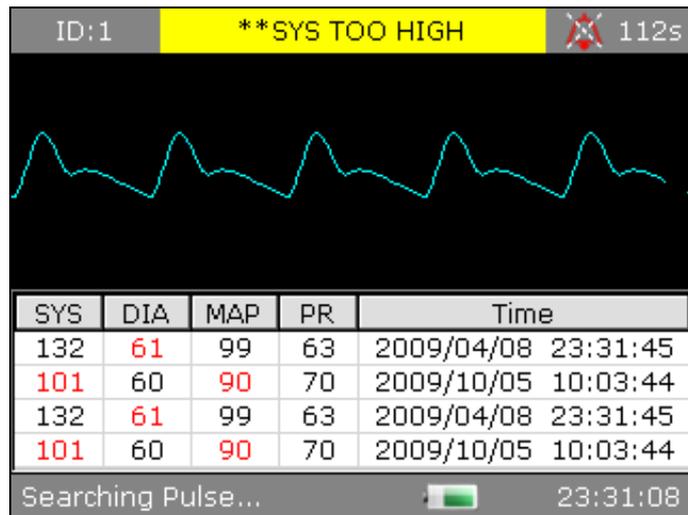


Figure 3-3 NIBP Multi-group Review

Change the display on the screen to Trend list as follows:

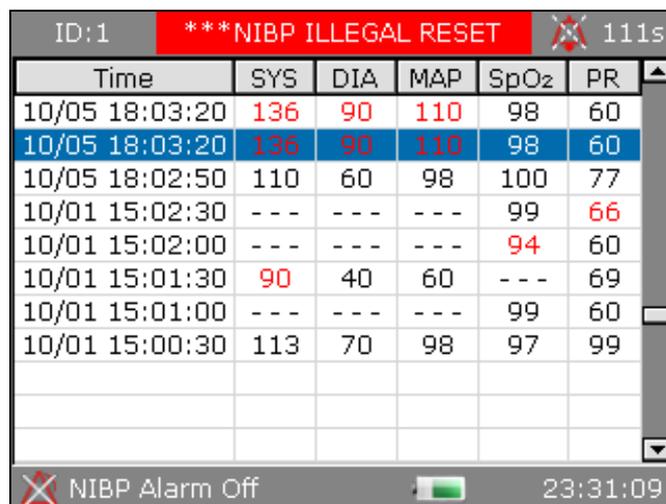


Figure 3-4 Display trend list

Change the display on the screen to Trend graph as follows:



Figure 3-5 Display SpO₂ trend graph

The icons on the interface and their meanings are as follows:

	Battery status indicator	
	Connected to mains power supply	
	Audio alarm off	
	Audio alarm paused	
	Parameter alarm off	
	Indicates an error occurs	
	Note	
	Warning	
	Password protection	
	Patient type: ADU (adult)	
	Patient type: PED (pediatric)	
	Patient type: NEO (neonatal)	
	Measuring oral TEMP	For device with the T2 TEMP module only.
	Measuring axillary TEMP	
	Measuring rectal TEMP	
	Measuring ear TEMP	For device with the Infrared Ear Temperature module (TH module) only.
ID	Current patient ID	

23: 31: 08	Current time
------------	--------------

Parameter Area (①)

Parameter area is on the upper part of main interface, and following parameters are displayed:

SpO₂:

- SpO₂ (Unit: %)
- PR (Pulse Rate, Unit: BPM).

NIBP:

- SYS, DIA, MAP (Unit: mmHg or kPa; 1mmHg=0.133kPa).
- Pulse Rate (Pulse Rate, Unit: BPM)

TEMP:

- Temperature (Unit: °C or °F).

The PR signal from SpO₂ measuring takes priority to be displayed.

Waveform/Trend List (②)

It can display SpO₂ waveform, NIBP multi-group review, trend list or trend graph.

Information Area (③ ④)

The Information Area is at the right and bottom parts of the screen, displaying operating status of the monitor and condition of the patient.

The information area contains the following data:

- Patient type and ID;
- NIBP measuring mode;
- Signs indicating the battery or mains power supply status;
- Current time;
- Alarms and prompts.

Alarm Indicator and Alarm Status

- In normal conditions, the alarm indicator does not light.
- When an alarm is generated, the alarm indicator lights or flashes. The color of light represents the alarm level. Refer to *Chapter 5 Alarm* for details.
- Refer to relevant content of parameters for Alarm information and prompt.

Charging Indicator and Charging Status

To indicate the status of charging: when the battery is being charged, the light turns to yellow; after the charge is finished, the light will be off.

3.2.2 Optional Displays

SpO₂ only measuring mode



Figure 3-6 Display in SpO₂ only mode

NIBP only measuring mode

In NIBP only measuring mode, the PR from NIBP measurement is also displayed on screen.



Figure 3-7 Display in NIBP only mode

3.3 Button Functions

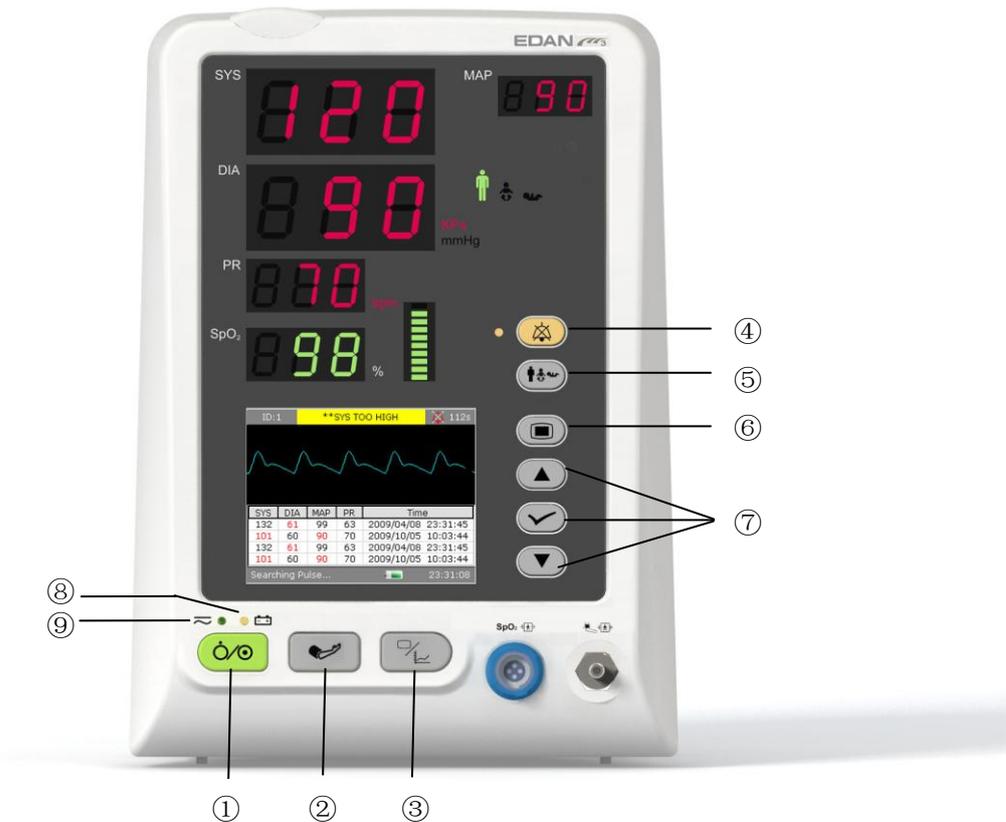


Figure 3-8 Buttons

All the operations to the monitor can be finished by several buttons.

<p>①</p>	<p>ON/OFF</p> 	<p>When the monitor is off, press this button to turn it on. When the monitor is on, press this button and hold for >3s to turn off the monitor; press this button, the menu for entering Standby Mode is displayed.</p>
<p>②</p>	<p>NIBP START/STOP</p> 	<p>To inflate the cuff and start blood measuring. During the measuring process, press the button to stop measuring. (For the monitor with NIBP function).</p>
	<p>ALARM LIMIT</p> 	<p>For SpO₂ only monitor, the NIBP STASRT/STOP button is changed to ALARM LIMIT button. Press this button to set the alarm limits of the parameters of SpO₂.</p>

③	TREND/WAVEFORM 	Press this button to switch among waveform display, trend list and trend graph display.
④	AUDIO ALARM PAUSED/OFF 	Press this button to pause or turn off the auditory alarm as needed.
⑤	PATIENT TYPE 	Press this button to change the patient type which is displayed on the front panel.
⑥	MENU 	Press to open the Main Menu . Refer to <i>Chapter 4 System Menu</i> for details.
⑦	UP  OK  DOWN 	Press UP or DOWN to select an item or to increase/decrease a number. Confirm the selection by pressing OK .

The icons on the front panel:

⑧	 CHARGE Indicator	The LED beside this icon indicates the charging status. When the battery is being recharged, the LED is bright.
⑨	 POWER Indicator	The LED beside this icon indicates the power condition. When the monitor connects to the mains power supply, the LED is bright.

3.4 Interfaces

For the convenience of operator, interfaces of different functions are in different sites of the monitor.

Sensor port on the front panel



Figure 3-9 Sensor Connectors

Connectors for cables and sensors are as shown in Figure 3-9.

1. SpO₂ sensor connector ①
2. NIBP cuff connector ②

WARNING

Only connect the device to EDAN supplied or recommended accessories.

Rear Panel

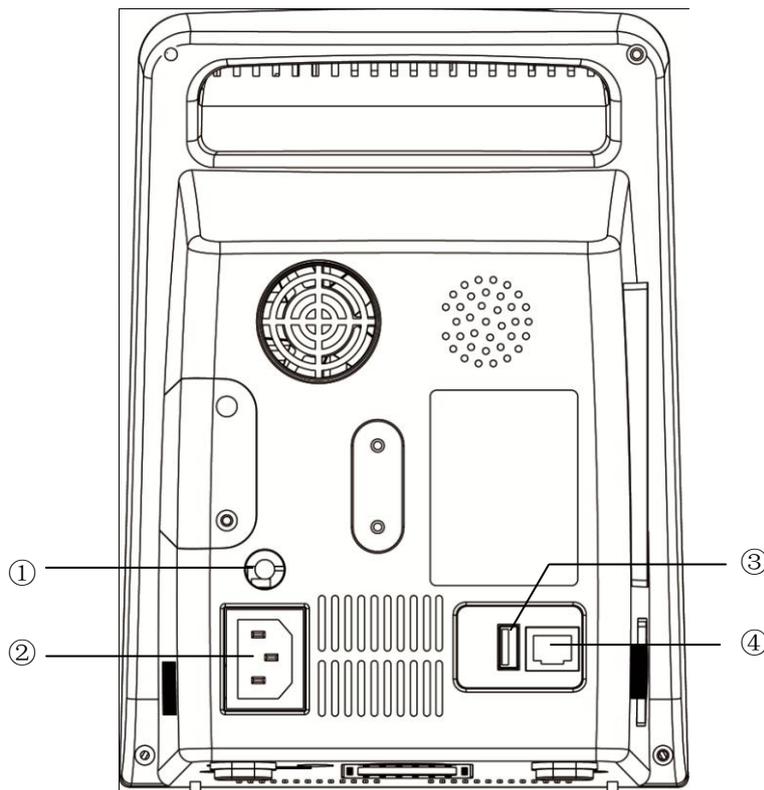


Figure 3-10 Rear Panel

Sockets on the rear panel are shown in the above figure:

- ① Equipotential grounding terminal for connection with the hospital's grounding system.
- ② Power supply socket: 100 V–240 V ~, 50 Hz/60 Hz.
- ③ USB connecting port for USB storage.
- ④ Network Interface: Standard RJ45 Socket, for connecting to MFM-CMS of EDAN

Bottom panel

There are battery compartment and fuse box on the bottom panel.

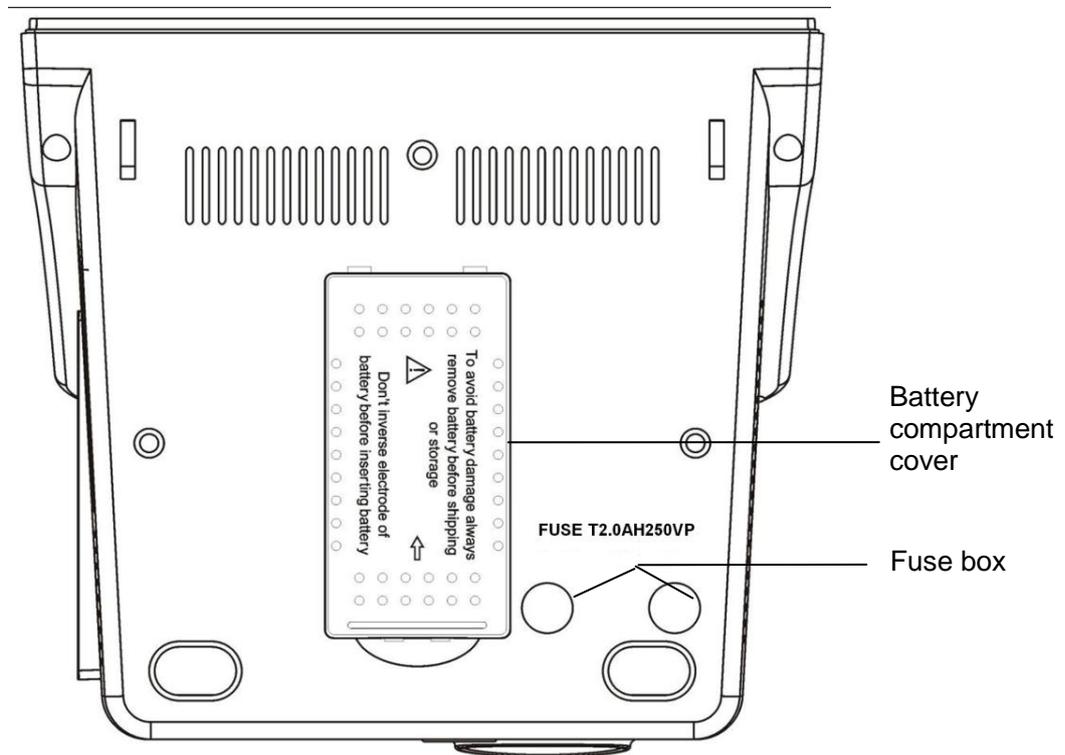


Figure 3-11 Bottom panel

3.5 Built-in Rechargeable Battery

3.5.1 Battery Safety Information

WARNING

- 1 Do not take off the battery when monitoring. The unexpected power supply off can not impact on the normal monitor working, if it has battery for standby.
- 2 Stop using the battery if abnormal heat, odor, discoloration, deformation or abnormal condition is detected during use, recharge, or storage. Keep it away from the monitor.
- 3 Make sure the monitor is used in the appointed range of voltage, so the effect of power supply can be ignored.
- 4 Before using the rechargeable lithium-ion battery (hereinafter called battery), be sure to read the user manual and safety precautions thoroughly.
- 5 Do not connect the positive (+) and negative (-) terminals with metal objects, and do not put the battery together with metal objects, which can result in short circuits.
- 6 Do not place battery in the monitor with the (+) and (-) in the wrong way around.

WARNING

- 7 Do not heat or throw battery into fire.
 - 8 Do not use, leave battery close to fire or other places where temperature may be above +60 °C. Do not immerse, throw, and wet battery in water/seawater.
 - 9 Do not destroy the battery, do not pierce battery with a sharp object such as a needle; do not hit with a hammer, step on or throw to cause strong shock; do not disassemble or modify the battery.
 - 10 Take out the battery before cleaning or storing the monitor for more than 1 month.
-
-

3.5.2 Battery Status on the Main Screen

The monitor is equipped with a built-in rechargeable battery. When switching on AC power supply, the battery will be recharged automatically until full electric energy. There is a sign  or  in the bottom right corner of screen.

- When the monitor is working with AC mains power, and it has no battery or the battery has full electric energy, it displays ;
- When the monitor is working with AC mains power, and the battery is being recharged, it displays ;
- When the monitor is working with battery, it displays .

If the monitor is off, you can see recharging status from the charger indicator. The battery status indicator is light in yellow when being recharged, and off when full.

Battery status symbols show the status of battery and battery power remaining:

-  Remaining battery power: 100%.
-  Remaining battery power: 75%
-  Remaining battery power: 50%
-  Remaining battery power: 25%
-  Batteries are almost depleted and need to recharge immediately.

3.5.3 Checking Battery Performance

The performance of rechargeable batteries may deteriorate over time. Battery maintenance as

recommended here can help to slow down this process.

1. Disconnect the patient from the monitor and stop all monitoring and measurement.
2. Switch the monitor power on and charge the battery for more than 6 hours continuously.
3. Disconnect monitor from mains power and let the monitor run until there is no battery power left and the monitor shuts off.
4. The running time of the battery reflects the battery performance.

If the running time is obviously less than the specified time in the specification, please change the battery or contact the service personnel.

3.5.4 Replacing the Battery

In monitoring or communication state, the battery status indicator will flash when the battery is low or empty.

When the lifespan of battery is over, foul odor or leakage is detected, please contact the manufacturer or local distributor for replacement of battery.

3.5.5 Recycling the Battery

When the battery no longer holds a charge, it should be replaced. Remove the old battery from the monitor and recycle it properly.

3.5.6 Maintaining the Battery

Batteries should be conditioned regularly to maintain their useful life.

Remove the batteries from the monitor if they are not used for a longer period of time. And recharge the batteries at a minimum of every 6 months when they are stored.

Discharge the battery completely once every month.

NOTE:

To prolong the life of rechargeable battery, it is recommended to charge it at least once every month, and it must be done after the electric energy runs out.

3.5.7 Battery Alarm Information

Technical Alarm:

Message	Cause	Alarm Level	What to do
Battery Low	Battery Low	High	Change the battery or charge the battery.

Chapter 4 System Menu

The monitor features in flexible configurations. You can configure various aspects of the monitor, including the parameters to be monitored, audio signal volume, and output content.

Press the **MENU** button on the front panel to open **Main Menu**. You can perform the following operations in this menu.

4.1 Patient Setup

Click on **Patient Setup** in **Main Menu** to open the menu.

You can set the following patient information:

- ◆ **Patient ID:** you can set the patient ID to 1 ~ 200.
- ◆ **Patient Type:** you can set the patient type to **Adult**, **Pediatrics** or **Neonate**.

Press the **UP/DOWN** button on front panel to select the items, then press the **OK** button to confirm.

Select **Exit** to return to the previous menu.

4.2 NIBP Setup

Please refer to *9.3 NIBP Setup* for more information.

4.3 SpO₂ Setup

Please refer to *8.8 SpO₂ Setup* for more information.

4.4 TEMP Setup

Please refer to *10.1.3* or *10.2.3 TEMP Setup* for more information.

4.5 Alarm Setup

Refer to *5.1.3 Alarm Setup*.

4.6 Data Management

Select **Maintenance** in **Main Menu** to open the menu.

- ◆ **Start Data Transmission:** select this item to start transmitting data from monitor to data management software.
- ◆ **Clear Trend List-Clear Current ID:** Select this item to clear current ID.
- ◆ **Clear Trend List-Clear All ID:** select this item to clear all ID.

Please refer to *Chapter 6.1 Trend List* for details.

4.7 Recorder

Select **Recorder** in **Main Menu** to open the menu.

- ◆ **Record Realtime Data:** Select it to output the real time data from the monitor.
- ◆ **Record Trend Graph:** Select it to output the trend graph.
- ◆ **Record Current Trend Table:** Select it to output the current trend table.
- ◆ **Record History Trend Table:** Select it to output the history trend table.

Please refer to *Chapter 6 Recording* for more information.

4.8 System Setup

There are a few items to be set in this submenu: **General Setup**, **General Alarm Setup**, **Time&Date Setup**, and **Default Configuration**.

4.8.1 General Setup

Select **General Setup** in **System Setup** to open submenu as below:

- ◆ **Key Volume:** set key volume to level **0 ~ 5**.
- ◆ **LCD Brightness:** set LCD brightness to level **1 ~ 5**.
- ◆ **Standby Mode:** set to **ON** or **OFF**. If you set this item to **ON**, when pressing **ON/OFF** button for less than 1s, the monitor will enter Standby Mode. (Please refer to *4.10 Standby Mode* for more information.)
- ◆ **Work Mode:** set to **Spot** or **Monitor**.

4.8.2 General Alarm Setup

Select **General Setup** in **System Setup** to open submenu as below

- ◆ **Alarm Volume:** set alarm volume to level **1 ~ 5**.

4.8.3 Time & Date Setup

Select **Time & Date Setup** in **Main Menu** to access the submenu. System time is in format of **yy-mm-dd**, **mm-dd-yy** or **dd-mm-yy**. Users can set the year, month, day, hour, minute and second. Select the item you want to modify and confirm it by pressing **Confirm**. Select **Cancel** item to save the setup and return to the previous menu. If you want to exit the menu without saving it, press the **MENU** button on front panel.

4.8.4 Default Configuration

NOTE:

Select any item in this submenu to cancel the current setup and use the selected default setup.

- ◆ **Factory Default Config:** select the factory default configuration;

- ◆ **User Default Config:** select the user-defined default configuration;
- ◆ **Restore Selected Config:** select this item to restore the selected configuration;

4.9 Maintenance

Select **Maintenance** in **Main Menu** to open the menu. **Factory Maintenance** is only available for the service personnel of EDAN or representatives authorized by EDAN.

User Maintenance

Input the user password **9 9 8 1** in the **Enter Password** box and press **Confirm**:

User Maintenance menu will pop up, in which you can set the following items.

- ◆ **Language:** Set the displaying language.

NOTE:

The user should restart the monitor after changing the displaying language.

- ◆ **Nurse Call:** Turn on or off the nurse call. When the parameter alarm occurs, the monitor gives a 3s nurse call alarm prompt; if the audio alarm or the audio system is off, the monitor can also give the nurse call alarm in abnormal condition.

The relay contact between pin7 and pin8 of RJ45 is normally open. But it is closed when an alarm is audible.

- ◆ **NIBP Setup**
- ◆ **NIBP Memory**

You can set this item to **ON** or **OFF**. If the item is **ON**, the monitor will automatically memorize the initial measurements of the patient when measuring his or her blood pressure. Then the monitor will inflate the cuff according to the previous memorized measurements. This function accelerates the measuring of the patient's blood pressure.

- ◆ **AVG Interval:** Set the average NIBP measurement interval to **1min, 2min, 3min, 4min** or **5min**.
- ◆ **AVG Times:** Set the average NIBP measurement times to **3** or **5**.
- ◆ **NIBP Reset:** select it to reset the NIBP module.

Restore measurement status.

Pick this item to restore initial settings of the pressure pump.

When the pressure pump does not work properly and the system fails to give message for the problem, pick this item to activate self-test procedure, thus restore the system from abnormal performance.

- ◆ **Calibration:**

Calibrate the cuff pressure reading with a calibrated reference manometer. Pick the **Calibration** item to start the calibration and the item will change into **STOP CAL**, which if picked, the system will stop calibration.

WARNING

The calibration of the NIBP measurement is necessary every two years (or as frequently as dictated by your Hospital Procedures Policy). The performance should be checked according to the following details.

Procedure of the Pressure Transducer Calibration:

Replace the cuff of the monitor with a rigid metal vessel with a capacity of (500 ± 25) ml. Connect a calibrated reference manometer with an error less than 0.8mmHg and a ball pump by means of a T-piece connector and hoses to the pneumatic system. Select **Calibration** in menu. Inflate the pneumatic system to 0mmHg, 50mmHg and 200mmHg by ball pump separately. The difference between the indicated pressure of the reference manometer and the indicated pressure of the monitor will not exceed 3mmHg. Otherwise, please contact our customer service.

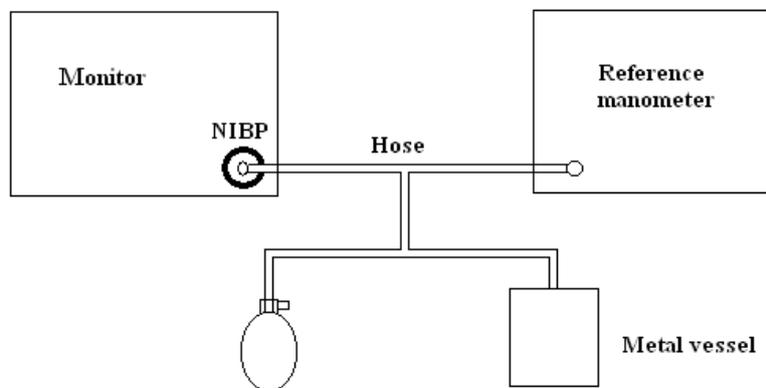


Figure 4-1 NIBP Calibration

◆ Leak Test

This item is used for air leakage test. Press this item to start the air leakage test. Then the item will change into **Stop Leakage Test**. If it is picked again, the system will stop air leakage test.

WARNING

This leakage test other than being specified in the IEC/EN1060-1 standard is to be used by the user to simply determine whether there are air leaks in the NIBP airway. If at the end of the test the system gives the prompt that the NIBP airway has air leaks, please contact the manufacturer for repair.

Procedure of the Air Leakage Test:

- 1) Connect the cuff securely with the socket for NIBP air hole.
- 2) Wrap the cuff around the cylinder of an appropriate size.
- 3) Access the **NIBP Setup** menu.
- 4) Select the **Leakage Test** item by pressing the **UP/DOWN** button. It displays indicates **Leakage Test** on the bottom of the parameter area.

- 5) The system will automatically inflate the pneumatic system to about 180mmHg.
- 6) After 20s or so, the system will automatically open the deflating valve, which marks the completion of a pneumatic measurement.
- 7) If no prompt appears on the bottom of the NIBP parameter area, it indicates that the airway is in good status and no air leaks exist. However if the prompt AIR LEAK appears in the place, it indicates that the airway may have air leaks. In this case, the user should check for loose connection. After confirming secure connections, the user should re-perform the pneumatic test. If the failure prompt still appears, please contact the manufacturer for repair.

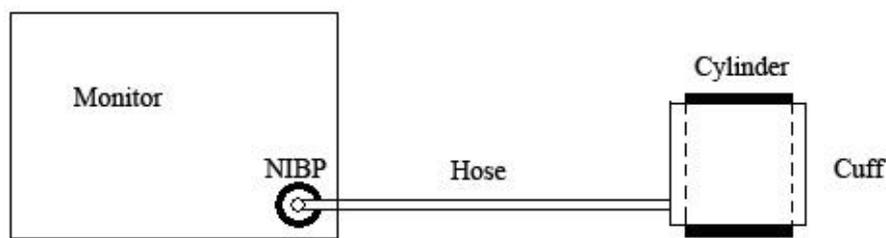


Figure 4-2 Diagram of NIBP Air Leakage Test

- ◆ **SpO₂ Setup**
- ◆ **Sensitivity**

The SpO₂ reading is the average of data collected within a specific time. You can set **Sensitivity** to **Low**, **Medium** or **High** via the menu. The higher the sensitivity is, the quicker the pulse oximeter responds to the changes in the patient's oxygen saturation level. Contrarily, the lower the sensitivity is, the slower the pulse oximeter responds to the changes in the patient's oxygen saturation level, but the measurement accuracy will be improved. When a critical patient is monitored, selecting high sensitivity will help to understand the patient's state.

- ◆ **Sensor Off**

You can configure the alarm level for SpO₂ **Sensor Off** to **Low** or **High**.

- ◆ **Alarm Setup**

Audio Alarm Paused

To activate the auditory alarm function, you can set **Audio Alarm Paused** to any value: **60s**,

120s or **180s**, then press the button  on the front panel to pause audio alarm. The information area displays the remaining pause time in seconds. Key sounds and beat sounds keep their previous status. Auditory alarm will resume when you press the button



again or the pause time terminates.

- ◆ **Audio Alarm Off**
- ◆ To activate the Audio Alarm Off function, you can set **Audio Alarm Off** to **ON**, then press

the button  on the front panel and hold it for more than three seconds to turn off auditory alarm. Key sounds and beat sounds keep their previous status. Press the button  again to resume auditory alarm. If you set **Audio Alarm Off** to **OFF**, the function is inactivated.

- ◆ **Alarm Record** (only available for the monitor outfitted with a recorder)

By configuring **Alarm Record**, the function of automatically outputting the alarm information in case of any physiological alarm can be enabled or disabled. If the item is **ON**, the monitor will automatically print out the alarm information once any physiological alarm is triggered. If the item is **OFF**, the monitor will not automatically output the alarm information.

- ◆ **Other Setup**

- ◆ **Net Setup**

Access **Net Setup** and you can see the menu:

Bed No.: Set the bedside monitor number to a value from 1~64.

Server IP

The default server IP is 202.114.4.119. It can be changed by the user according to the IP of PC installed with MFM-CMS of EDAN.

Server Port: Set the server port.

- ◆ **Barcode Setup**

ID Start/ID End:

You can determine which digit in the barcode is the starting/ending digit for the patient ID via configuration of **ID Start** and **ID End**.

Patient Type:

You can determine which digit in the barcode indicates the patient type. For example, if you set **Patient Type** to **1**, the first digit in the barcode will be identified as an indication of patient type.

Auto:

If it is set to **ON**, the patient information is updated automatically by using a barcode scanner. If it is set to **OFF**, a message box indicating “**Confirm to update patient, yes?**” will pop up when scanning a barcode. Click on **YES** to automatically update patient information; click on **NO** to quit automatical update.

Adult/ Pediatrics/ Neonate:

Select a digit from 0~9 to indicate the patient type.

NOTE:

- 1 Barcodes containing characters other than digits or containing space will be considered invalid and cannot be identified. If any invalid character is detected, a message box indicating “**Special signs in barcode!**” will appear.
- 2 Make sure the patient ID number obtained from the barcode is within the range of

patient ID stored in the monitor, or a message box indicating “**Invalid patient ID!**” will appear.

- 3 Connect the barcode scanner to the monitor and wait 10 seconds before starting the scanner.
 - 4 Refer to the accompanying operator’s manual of the scanner for more information about its usage.
- ◆ **Save as User Default Config:** save the current setup as the user default configuration;
 - ◆ **Exit:** Exit the menu.

Factory Maintenance

Factory maintenance function is only available for the service personnel of EDAN or representative authorized by EDAN.

Version

Select **Main Menu > Maintenance > About** to check the version of the modules.

4.10 Standby Mode

Entering Standby Mode

When the monitor is on, press the **ON/OFF** button, the dialog box displays: **Sure to enter standby mode?(Press any key to return).**Select **YES** to enter the standby mode.

In the following two conditions, the monitor can not enter standby mode.

1. If the monitor is measuring, press the **ON/OFF** button for less than 2 seconds, the dialog box displays: **Cannot enter standby mode while measurement going...**
2. If the battery is low, press the **ON/OFF** button for less than 2 seconds, the dialog box displays: **Cannot enter standby mode due to BATTERY LOW alarm!**

Quitting Standby Mode

In Standby Mode, press any button on the front panel to quit standby mode.

NOTE:

- 1 In the following situations, the monitor will return to normal monitoring mode automatically: The monitor receives physiological signal of SpO₂, and lasts for 5s; If the monitor is powered by battery, when the battery electric energy is low, it will enter normal monitoring mode, and indicates low battery alarm.
- 2 In DEMO mode, the monitor can not enter standby mode.

Chapter 5 Alarm

This chapter gives general information about the alarm and measures to be taken accordingly. Alarm setup and prompt messages are provided in respective parameter setup sections.

WARNING

A potential hazard can exist if different alarm presets are used for the same or similar equipment in any single area.

5.1 Alarm Modes

5.1.1 Alarm Level

Each alarm, either technical or physiological, has its own level. For an alarm of a higher level, when the alarm is activated, the system will give a prompt in various ways. The alarm's level can not be changed by the user once defined by the system. Alarms in the monitor are divided into three levels: High, Medium and Low.

High-level alarm indicates the patient's life is in danger or the monitor has serious technical problems. It is a most serious alarm.

Medium-level alarm means serious warning.

Low-level alarm is a general warning.

The monitor provides two types of alarm: physiological alarms and technical alarms. Also, the monitor provides prompts. Physiological alarms refer to those alarms triggered by patient's physiological situation which could be considered dangerous to his or her life. Technical alarms refer to system failure which can make a certain monitoring process technically impossible or make monitoring result unbelievable. The monitor can give the character indication of monitoring process or other functions. And this character is called prompts.

All technical alarms and some of the physiological alarms are preset in the system and can not be changed by the user.

5.1.2 Alarm Modes

When an alarm occurs, the monitor can raise the user's attention in at least three ways, which are audio prompt, visual prompt and description.

Audio and visual prompts are given by LCD display device, the speaker on the display device and the alarm indicator. Physiological alarm, technical Alarm or description is displayed in information area or beside the parameters at the bottom of the screen.

NOTE:

The concrete presentation of each alarm prompt is related to the alarm level.

Screen display

When the measured parameter exceeds its alarm limits and triggers a physiological alarm, the alarm prompt will display on the screen of the monitor.

The description will display in Information area, such as “*****SYS TOO HIGH**” to indicate the low-medium level alarm.

Technical alarm will not prompt * signal.

Alarm Level	Visual Prompt
High	*** displays in information area of LCD (Physiological alarm only)
Medium	** displays in information area of LCD (Physiological alarm only)
Low	* displays in information area of LCD (Physiological alarm only)

Lamp light

The high/medium/low-level alarms are indicated by the system in the following different visual ways:

Alarm Level	Visual Prompt
High	Alarm indicator flashes in red with the frequency of (1.4-2.8) Hz.
Medium	Alarm indicator flashes in yellow with the frequency of (0.4-0.8) Hz.
Low	Alarm indicator lights on in cyan.

Alarm sound

The high/medium/low-level alarms are indicated by the system in the following different audio ways:

Alarm Level	Audio Prompt
High	Mode is “beep-beep-beep-----beep-beep, beep-beep-beep-----beep-beep”, which is triggered once every 5 s.
Medium	Mode is “beep-beep-beep”, which is triggered once every 25 s.
Low	Mode is “beep-”, which is triggered once every 30 s.

The sound pressure of auditory alarm is in the range of 45 dB ~ 85 dB.

WARNING

Do not rely exclusively on the audible alarm system for patient monitoring. Adjustment of alarm volume to a low level or off during patient monitoring may result in patient danger. Remember that the most reliable method of patient monitoring combines close personal surveillance with correct operation of monitoring equipment.

NOTE:

- 1 The monitor does not have alarm condition delay or alarm signal generation delay.
- 2 When alarms of different levels occur at the same time, the monitor prompts one of the highest levels.
- 3 If the monitor is powered off and then turned on, the alarm setup can resume to the setup which is set before the power-off.

5.1.3 Alarm Setup

Set **Alarm Setup** in **Main Menu** to open the submenu. The user can turn **ON** or **OFF** the alarm for each parameter, and set the upper alarm limit and lower alarm limit for each parameter by **High** or **Low**.

■ Alarm setup of each parameter

In the **Alarm Setup** menu, set the alarm limit for each parameter: **SYS, DIA, MAP, SpO₂, PR**. For example: Method to set systolic blood pressure alarm limit for **SYS** alarm:

Step 1: Set **SYS** to **ON**;

Step 2: Set **High** (higher limit of **SYS** alarm) and **Low** (lower limit of **SYS** alarm).

The user can press the **UP/DOWN** and **OK** button to set the menu.

The method for setting the alarm limits of other parameters is the same as **SYS** alarm.

WARNING

- 1 If the user set alarm to **OFF**, the monitor will not give alarm prompts when an alarm is activated, the user should use this function cautiously.
 - 2 The user should check the alarm limit to ensure it is proper for each patient.
-
-

5.2 Alarm Cause

Alarm occurs when:

1. Physiological alarm is evoked;
2. Technical alarm) is evoked;

■ A. Conditions that activate the parameter alarms:

The measurement value exceeds the alarm limit and the alarm is set to **ON**. Alarms will not be activated if the alarm is set to **OFF**.

■ B. Conditions that activate the system alarms (technical alarm):

Upon the system error, the monitor prompts alarm immediately.

■ C. General alert

In some circumstances, alerts will behave as physiological alarms in normal senses, we do not regard them as real patient health related items.

5.3 Audio Alarm Paused

To activate the audio alarm paused function, you can select **Main Menu > Maintenance > User Maintenance > Alarm Setup**, and set **Audio Alarm Paused** to **60 s**, **120 s** or **180 s** (The default duration of auditory alarm pause is 120 s), as follows:

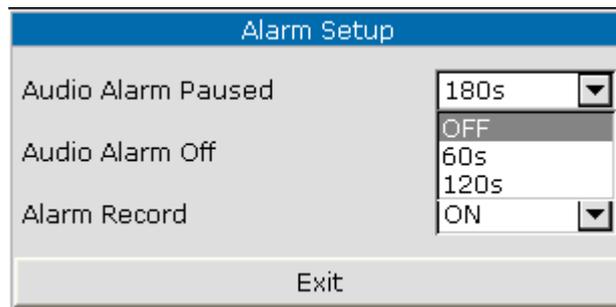


Figure 5-1 Alarm Setup

Then press the button  for less than 2 s to pause audio alarm.

During the audio alarm paused status:

- ◆ In the information area, the monitor displays audio alarm off icon  and audio alarm paused **XXXs**.
- ◆ The audio alarm (including technical alarm and physiological alarm) is paused, and no alarms are sounding, the visual alarm indications are still displayed.
- ◆ The audio alarm paused/off indicator on the front panel flashes in yellow, with interval of 1s.
- ◆ Other audible signals are not affected, including beat volume, key volume.

Auditory alarm will resume when you press the button  again or the paused time terminates.

When **Audio Alarm Paused** is set to **OFF**, this function is inactivated. The monitor has no response if you press the button .

NOTE:

If a new alarm occurs during the audio alarm paused status, the new alarm will not be sounding.

5.4 Audio Alarm Off

To activate the audio alarm off function, you can select **Main Menu > Maintenance > User Maintenance > Alarm Setup**, and set **Audio Alarm Off** to **ON**, as follows:

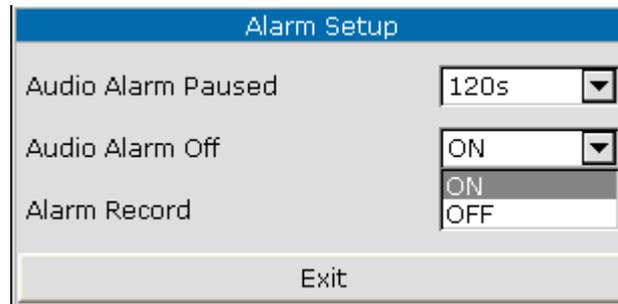


Figure 5-2 Alarm Setup

Then press the button  and hold it for more than three seconds to turn off audio alarm. During the audio alarm off status,

- ◆ In the information area, the monitor displays the audio alarm off icon 
- ◆ The audio alarm paused/off indicator on the front panel always flashes.
- ◆ The audio alarm (including technical alarm and physiological alarm) is turned off, and no alarms are sounding. The visual alarm indications are still displayed.
- ◆ Other audible signals are not affected, including beat volume, key volume.

Pressing the button  again can resume the audio alarm.

When **Audio Alarm Off** is set to **OFF**, this function is inactivated. The monitor has no response if you press the button .

NOTE:

If a new alarm occurs during the audio alarm off period, the new alarm will not be sounding.

5.5 Alarm Reset

To reset the alarm, you can select **Main Memu > Alarm Setup> Alarm Reset**. After resetting the alarm,

- ◆ The audio alarm (including technical alarm and physiological alarm) is turned off, and no alarms are sounding.
- ◆ The visual alarm indications are still displayed.
- ◆ It will not influence the configuration of physiological alarm off, audio alarm paused and audio alarm off status.

NOTE:

If a new alarm occurs after the alarm is reset, the new alarm will be sounding.

5.6 Parameter Alarm

WARNING

- 1 Prior to monitoring, make sure that the alarm limit settings are appropriate for your patient.
 - 2 Setting alarm limits to extreme values may cause the alarm system to become ineffective.
-
-

In **Main Menu** > **Alarm Setup**, you can check and set the alarm limit or alarm status. The setup is isolated from each other.

When a parameter alarm is **OFF**, an icon  displays near the parameter. If the alarms are turned off individually, they must be turned on individually.

For the parameters whose alarm is set to **ON**, the alarm will be triggered when at least one of them exceeds alarm limits. The following actions take place:

1. Alarm message displays on the screen as described in alarm mode;
2. The monitor beeps in its corresponding alarm class and volume;
3. Alarm lamp flashes.

5.7 When an Alarm Occurs

NOTE:

When an alarm occurs, you should always check the patient's condition first.

The alarm message appears in Information area of the screen. It is needed to identify the alarm and act appropriately, according to the cause of the alarm.

1. Check the patient's condition.
2. Identify the cause of the alarm.
3. Identify which parameter is alarming or which alarm is happening.
4. When the cause of the alarm is cleared, check that the alarm is working properly.

You will find the alarm messages for the individual parameters in their appropriate parameter chapters of this manual.

5.8 Testing Alarms

When you switch the monitor on, a selftest is started. You must check that the alarm indicator lights and that you hear a single tone. This indicates that the visible and audible alarm indicators are functioning correctly. For further testing of individual measurement alarms, perform the measurement on yourself or use a simulator. Adjust alarm limits and check that appropriate alarm behavior is observed. .

Chapter 6 Trend and Recording

6.1 Trend List

The NIBP Multi-Group list is displayed as follows:

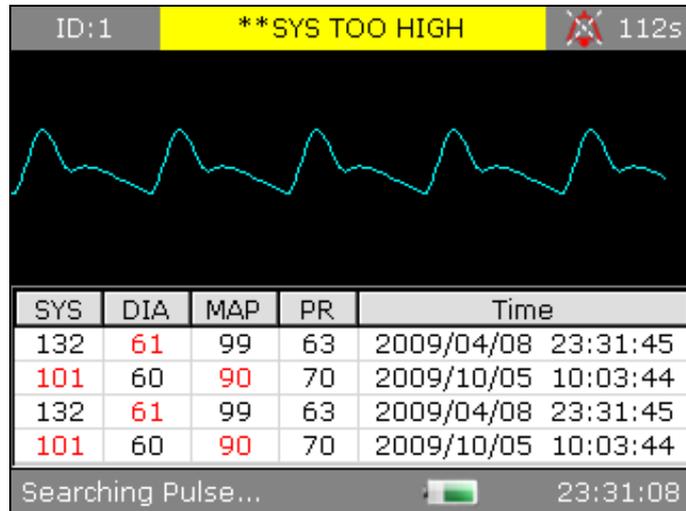


Figure 6-1 NIBP Multi-Group Review

Press **TREND/WAVEFORM** button to change the waveform to trend list.

Select **Main Menu>Data Management**, display: **Start Data Transmission, Clear Trend List-Clear Current ID, Clear Trend List-Clear All ID**.

Select **Clear Trend List-Clear Current ID**, display the dialog box: **Clear Current ID?**

Select **Clear Trend List-Clear All ID**, display the dialog box: **Clear All ID?**

When deleting all data, the process bar is displayed: **Clearing data 50%...**

6.2 Trend Graph

Press the **TREND/WAVEFORM** button to change the displaying list to trend graph of NIBP/SpO₂/PR as follows:



Figure 6-2 SpO₂ Trend Graph

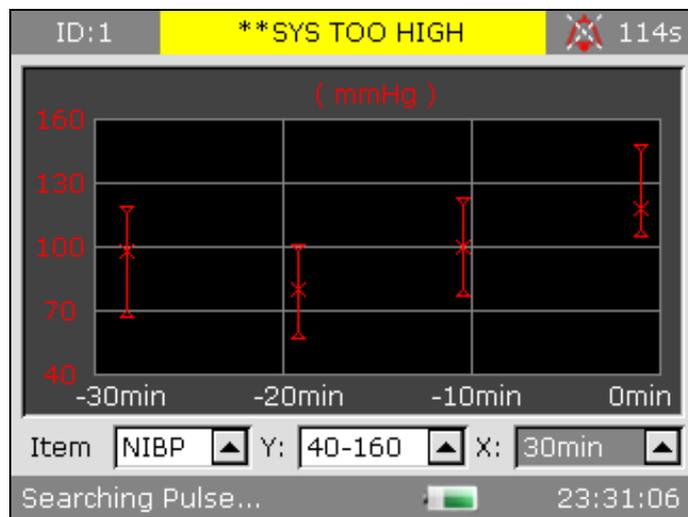


Figure 6-3 NIBP Trend Graph

You can set the items below the trend graph.

Item: you can set the display parameter to **NIBP**, **SpO₂** or **PR**.

Y: it stands for the ordinate which indicates the displayed data range.

X: it stands for the abscissa which indicates the displayed time range.

After selecting the **NIBP**, **SpO₂** or **PR**, the **Y** and **X** can be set as the following table shows:

Parameter	Y (data range)	X (time range)
SpO ₂	0~100, 60~100, 80~100	30 min / 60 min / 120 min
NIBP	10~270, 20~180, 40~160	30 min / 60 min / 120 min
PR	30~300, 40~180, 40~120	30 min / 60 min / 120 min

6.3 Recording

A thermal dot matrix recorder is used for the monitor. It supports the printout of real time data, trend graph and trend table.

6.3.1 Recorder Operations

Requirement for the Recording Paper

Use only specified thermal paper. The use of any other paper can result in malfunction of the recorder, poor recorder performance or damage to the thermal printhead

Proper Operation

- ◆ When the recorder is working, the recording paper goes out steadily. Do not pull the paper outward with force; otherwise the recorder may be damaged.
- ◆ Do not operate the recorder without recording paper in the compartment.

Paper Out

When the alarm prompt **OUT OF PAPER** is displayed onscreen, the recorder can not start. Please load recording paper properly.

Replacing Paper Supply

1. Hold the upper arc part of the recorder door and pull it outwards to open the door.
2. Insert a new roll of paper into the compartment with the printable surface of the paper facing upwards.
3. Make sure that the paper is properly loaded with the edge of paper paralleling with the edge of the recorder door.
4. Ensure that a minimum of 2 cm of paper extends beyond the edge of the recorder door.
5. Close the recorder door.

NOTE:

- 1 Be careful not to insert paper with force, and avoid touching the printhead.
- 2 Do not leave the recorder door open unless when replacing paper or removing fault.

Removing Paper Jam

If the recorder works improperly or produces unusual sound, open the recorder door and check whether there is a paper jam. If yes, remove it following the procedure below:

1. Cut the paper from the feeding edge.
2. Open the recorder door.
3. Reload the paper and close the recorder door.

6.3.2 Outputting the Monitoring Data

By selecting the items on **Main Menu > Recorder**, you can output the real time data, trend graph current trend table and history trend table.

- ◆ **Record Realtime Data:** Select this item, and the recorder will output the real time data including measurements and SpO₂ waveforms.
- ◆ **Record Trend Graph:** Select this item, and the recorder will output the trend graph.
- ◆ **Record Current Trend Table:** Select this item, and the recorder will output the current trend table.
- ◆ **Record History Trend Table:** Select this item, and the recorder will output the history trend table.

Press the button **UP** or **DOWN** on the front panel to select an item among the above-mentioned

items from the menu, and press  on the front panel to confirm it. Subsequently, the recorder will start outputting the monitoring data. Meanwhile, the selected item will be changed into **Stop Record**.

You can stop the current recording process by select **Stop Record** on the menu.

NOTE:

Do not use the recording function when a low battery alarm occurs, or automatic shutdown of the monitor may result.

6.3.3 Recorder Alarm Information

Technical Alarm:

Message	Cause	Alarm Level	What to do
Recorder Out Of Paper	Recorder Out Of Paper	Low	Please install the paper.
Recorder setup needed	The user presses the RECORD button when the monitor is not installed with a recorder.	Low	Notify the manufacturer's service staff to install and set the recorder.

Chapter 7 Maintenance and Cleaning

WARNING

- 1 Failure on the part of the responsible individual hospital or institution employing the use of this equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazards.
- 2 If you discover a problem with any of the equipment, contact your service personnel, or your authorized supplier.

7.1 Inspecting

The overall check of the monitor, including the safety check, should be performed only by qualified personnel every 24 months, and each time after fix up.

The following items should be checked:

- If the environment condition and power supply meet requirement.
- If the power supply cord has damage and insulativity meets requirement.
- If the device and accessories have damage.
- Specified accessories.
- If the alarm system can work properly.
- If the recorder can work properly and the paper meets the requirement.
- Battery performance
- If all monitoring functions are in good conditions.
- If the grounding resistance and leakage current meet requirement.

If any damage or abnormality is found, please don't use the monitor and contact local Customer Service Center.

7.2 Maintenance Task and Test Schedule

Maintenance shall be carried out at least once every two years, or as specified by local regulations. The following tasks are for EDAN-qualified service professionals only. Contact an EDAN-qualified service provider if your monitor needs a safety or performance test. Clean and disinfect equipment to decontaminate it before testing or maintaining it.

Maintenance and Test Schedule	Frequency
Safety checks. Selected tests on the basis of IEC60601-1	At least once every two years, or as needed, after any repairs where the power supply is removed or replaced, or if the monitor has been dropped.

Maintenance and Test Schedule	Frequency
Check all monitoring functions and measuring functions	At least once every two years, or as needed.

7.3 General Cleaning

If the device or accessory has been in contact with the patient, then cleaning and disinfection is required after every use. If there has been no patient contact and there is no visible contamination then daily cleaning and disinfection is appropriate.

The validated cleaning agents for cleaning the monitor and reusable accessories are:

- Mild near neutral detergent
- Ethanol (75%)
- Isopropanol (70%)

Cleaning agents should be applied and removed using a clean, soft, non-abrasive cloth or paper towel.

7.3.1 Cleaning the Monitor

WARNING

Before cleaning the monitor, make sure that the monitor is switched off and disconnected from the power line.

To surface-clean the monitor, follow these steps:

1. Switch off the monitor and disconnect it from the power line.
2. Wipe the entire exterior surface, including the screen, of the equipment using a soft cloth dampened with the cleaning solution thoroughly until no visible contaminants remain..
3. Wipe off the cleaning solution with a fresh cloth or towel, dampened with tap water after cleaning until no visible cleaning agent remains..
4. Dry the monitor in a ventilated and cool place.

7.3.2 Cleaning the Reusable Accessories

7.3.2.1 Cleaning the Blood Pressure Cuff

Cleaning the Cuff:

5. Take out the air bladder before cleaning.
6. Hand wash the cuff with the cleaning solution; clean the air bladder with a soft cloth dampened with the cleaning solution. until no visible contaminants remain.
7. Rinse the cuff and wipe off the cleaning solution with a fresh cloth or towel, dampened with

tap water after cleaning until no visible cleaning agent remains.

8. Wipe off with a dry cloth to remove residual moisture
9. Air dry the cuff thoroughly after cleaning.

Replacing the Air Bladder:

After cleaning, replace the air bladder into the cuff following the steps below:

10. Roll the bladder lengthwise and insert it into the cuff from the large opening at one end of the cuff.
11. Thread the hose from within the cuff and out through the small hole at the top of the cuff.
12. Adjust the bladder until it is in position.

7.3.2.2 Cleaning the SpO2 Sensor

13. Wipe the surfaces of the sensor and cable using a soft cloth dampened with the cleaning solution until no visible contaminants remain.
14. Wipe the patient contact area of the sensor with the cotton swab dampened with the cleaning solution. until no visible contaminants remain
15. Wipe off the cleaning solution with a fresh cloth or towel, dampened with tap water after cleaning until no visible cleaning agent remains.
16. Wipe off with a dry cloth to remove residual moisture.
17. Leave the sensor to air dry.

7.3.2.3 Cleaning the TEMP Sensor

18. Wipe the patient contact area with a soft cloth dampened with the cleaning solution until no visible contaminants remain.
19. Wipe off the cleaning solution with a fresh cloth or towel, dampened with tap water after cleaning until no visible cleaning agent remains.
20. Wipe off with a dry cloth to remove residual moisture.
21. Leave the sensor to air dry.

7.4 Disinfection

For devices or accessories that have been in contact mucosal surface, High Level disinfection must occur, for all other accessories, low level disinfection is appropriate. Clean the monitor and reusable accessories before they are disinfected. The validated disinfectants for cleaning the monitor and reusable accessories are:

- Ethanol (75%)
- Isopropanol (70%)
- Cidex OPA (High level disinfection of intracavitary temperature probe only)

If Ethanol or Isopropanol is used for both cleaning and disinfecting, then a new cloth is required to be used for the disinfection step.

WARNING

The monitor and reusable accessories shall be disinfected to avoid patient cross infection.

7.4.1 Disinfecting the Monitor

WARNING

Before disinfecting the monitor, make sure that the monitor is switched off and disconnected from the power line.

To disinfect the monitor, follow these steps:

22. Switch off the monitor and disconnect it from the power line.
23. Wipe the display screen using a soft, clean cloth dampened with the disinfectant solution.
24. Wipe the exterior surface of the equipment using a soft cloth dampened with the disinfectant solution.
25. Wipe off the disinfectant solution with a dry cloth after disinfection if necessary.
26. Dry the monitor for at least 30 minutes in a ventilated and cool place.

7.4.2 Disinfecting the Reusable Accessories

7.4.2.1 Disinfecting the Blood Pressure Cuff

Disinfecting the Cuff:

27. Take out the air bladder before disinfection.
28. Wipe the cuff and the air bladder with a soft cloth dampened with the disinfectant solution.
29. Leave the cuff and air bladder to air dry for at least 30 minutes.

NOTE:

Prolonged use of disinfectant may cause discoloration of the cuff.

Replacing the Air Bladder:

After disinfection, replace the air bladder into the cuff. Refer to Section 7.3.2.1 for more information.

7.4.2.2 Disinfecting the SpO2 Sensor

30. Wipe the surfaces of the sensor and cable using a soft cloth dampened with the disinfection

solution.

31. Wipe the patient contact area of the sensor with the cotton swab dampened with the disinfection solution.
32. Wipe off the disinfection solution with a dry cloth after disinfection.
33. Leave the sensor to air dry for at least 30 minutes.

7.4.2.3 Disinfecting the TEMP sensor

The intracavitary TEMP sensors should be reprocessed by high-level disinfection before and after use on each new patient. Cidex OPA is the validated agent for high level disinfection. Refer to the instructions of the disinfectant for the methods of disinfection. High level disinfection has been validated with a 12 minute soak. Rinse and dry according to the labeled instructions of Cidex OPA. Do not dampen the sensor connector.

For the skin TEMP sensors, disinfect them as follows using ethanol or isopropanol only:

34. Wipe the patient contact area with a soft cloth dampened with the disinfectant solution (ethanol or isopropanol).
35. Wipe off the disinfectant solution with a dry cloth after disinfection.
36. Leave the sensor to air dry.

7.5 Replacement of Fuse

Unscrew the fuse cap anticlockwise, replace the fuse (protector tube) and screw down the fuse cap clockwise. Fuse size: $\Phi 5 \times 20$, Rated value: T 2.0 AH /250 VP.

NOTE:

Switch off the power of the monitor before examining the fuse.

7.6 Cleaning Battery and Battery Compartment Cover

Use only non-caustic detergents such as soap and warm water (40 °C /104°F maximum) to clean the battery. Do not use strong solvent to clean battery, and do not dip the battery in liquid.

Chapter 8 SpO₂ Monitoring (Optional)

8.1 What is SpO₂ Monitoring

The monitor uses oximetry to measure functional oxygen saturation in the blood. SpO₂ Plethysmogram measurement is employed to determine the functional oxygen saturation of hemoglobin in the arterial blood. For example, if 97% hemoglobin molecules in the red blood cells of the arterial blood combine with oxygen, then the blood has an SpO₂ oxygen saturation of 97%. The SpO₂ numeric on the monitor will read 97%. The SpO₂ numeric shows the percentage of hemoglobin molecules which have combined with oxygen molecules to form oxyhemoglobin. The SpO₂/PLETH parameter can also provide a pulse rate signal and a plethysmogram wave.

How the SpO₂/PLETH Parameter Works

- Arterial oxygen saturation is measured by a method called pulse oximetry. It is a continuous, non-invasive method based on the different absorption spectra of reduced hemoglobin and oxyhemoglobin. It measures how much light, sent from light sources on one side of the sensor, is transmitted through patient tissue (such as a finger or an ear), to a receiver on the other side.
- The amount of light transmitted depends on many factors, most of which are constant. However, one of these factors, the blood flow in the arteries, varies with time, because it is pulsating. By measuring the light absorption during a pulsation, it is possible to derive the oxygen saturation of the arterial blood. Detecting the pulsation gives a PLETH waveform and pulse rate signal.
- The SpO₂ value and the PLETH waveform can be displayed on the main interface.
- The sensor contains LEDs that emit red light at a wavelength of approximately 660 nm and infrared light at a wavelength of approximately 905 nm. The power of the sensor LED is less than 15 mW.

SpO₂/Pulse Monitoring

WARNING

- 1 ES (Electrosurgery) equipment wire and SpO₂ cable must not be tangled up.
 - 2 Do not put the sensor on extremities with arterial catheter or venous syringe.
 - 3 Pulse oximetry can overestimate the SpO₂ value in the presence of Hb-CO, Met-Hb or dye dilution chemicals.
-
-

NOTE:

- 1 Do not perform SpO₂ measuring and NIBP measuring on a same arm at one time, because obstruction of blood flow during NIBP measuring may adversely affect the reading of SpO₂ value.
- 2 The monitor should not be used under strong light, or the accuracy may not be satisfied.

8.2 Precautions during SpO₂/PR Monitoring

WARNING

- 1 Verify sensor cable fault detection before beginning of monitoring phase. Unplug the SpO₂ sensor cable from the socket, the screen will display the error message **SpO₂ SENSOR OFF** and the audible alarm is activated.
- 2 If the SpO₂ sensor can not work properly, please reconnect the sensor or change a new one.
- 3 Do not use the sterile supplied SpO₂ sensors if the packaging or the sensor is damaged and return them to the vendor.
- 4 Prolonged and continuous monitoring may increase the risk of unexpected change of dermal condition such as abnormal sensitivity, rubescence, vesicle, repressive putrescence, and so on. It is especially important to check the sensor placement of neonates and patients of poor perfusion or immature dermogram by light collimation and proper attaching strictly according to changes of the skin. More frequent examinations may be required for different patients.
- 5 Tissue damage may be caused by incorrect application or prolonged measurement duration using the sensor (more than 4 hours). Inspect the sensor periodically according to sensor user manual.
- 6 The sensor complies with the EN ISO 10993-1: 2009 for biocompatibility.

NOTE:

- 1 Make sure the nail covers the light window;
- 2 The wire should be on the backside of the hand;
- 3 Hand should not be too cold when measuring, and the nail polish should be cleaned before measuring, or the data accuracy may be affected.
- 4 SpO₂ waveform is not proportional to the pulse volume.
- 5 The accuracy of SpO₂ has been verified by clinical tests according to ISO9919. The monitor can only be used for SpO₂ measurement, not for accuracy assessment of other device.
- 6 Don't use the functional simulator to assess the SpO₂ accuracy.
- 7 When the SpO₂ value is potentially incorrect, it will display "---".

8.3 Monitoring Procedure

SpO₂ plethysmogram measurement

1. Connect the SpO₂ sensor and extension cable to the SpO₂ sensor port of monitor.
2. Switch on the monitor.
3. Enter **Patient Setup** menu to set **Patient Type** as required.
4. Attach the sensor to the appropriate site of the patient finger.
5. The measured SpO₂ is displayed on screen.

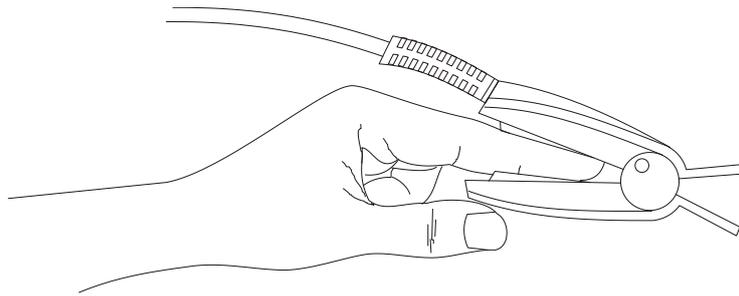


Figure 8-1 Mounting of the Sensor

8.4 Limitations of Measurement

In operation, the accuracy of oximetry readings can be affected by:

- High-frequency electrical noise, including noise created by the host system, or noise from external sources, such as electrosurgical apparatus, which is admitted by the host system.
- Do not use monitor and oximetry sensors during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns.
- Intravenous dye
- Excessive patient movement
- Outside ray radiation
- Improper sensor application
- Sensor temperature (maintain between +28 °C and +42 °C for best operation)
- Placement of the sensor on an extremity that has a blood pressure cuff, arterial catheter, or intravascular line
- Significant concentration of dysfunctional hemoglobin, such as carboxyhemoglobin and methemoglobin
- Low SpO₂.
- Circular perfusion is not good for test part
- It is recommended to use SpO₂ sensors described in *Chapter 12 Accessories and Ordering Information*.

8.5 Assessing the Validity of a SpO₂ Reading

You can check the quality of the pleth wave and the stability of the SpO₂ values to assess whether the sensor functions properly and whether the SpO₂ readings are valid. Always use these two indications simultaneously to assess the validity of a SpO₂ reading.

Generally, the quality of the SpO₂ pleth wave reflects the quality of the light signals obtained by the sensor. A wave of poor quality manifests a decline of the signal validity. On the other hand, the stability of the SpO₂ values also reflects the signal quality. Different from varying SpO₂ readings caused by physiological factors, unstable SpO₂ readings are resulted from the sensor's receiving signals with interference. The problems mentioned above may be caused by patient movement, wrong sensor placement or sensor malfunction. To obtain valid SpO₂ readings, try to limit patient movement, check the placement of the sensor, measure another site or replace the sensor.

NOTE:

- 1 The SpO₂ accuracy has been validated in human studies against arterial blood sample reference measured with a CO-oximeter. Pulse oximeter measurements are statistically distributed, only about two-thirds of the measurements can be expected to fall within the specified accuracy compared to CO-oximeter measurements. The volunteer population in the studies composed of local healthy men and women from age 19 to 37, with various skin pigmentations.
- 2 The pulse rate accuracy is obtained by comparison to the pulse rate generated with an arterial oxygen simulator (also an electronic pulse simulator).

8.6 SpO₂ Alarm Delays

There is a delay between a physiological event at the measurement site and the corresponding alarm at the monitor. This delay has two components:

1. The time between the occurrence of the physiological event and when this event is represented by the displayed numerical values. This delay depends on the algorithmic processing time and the sensitivity. The lower the sensitivity configured, the longer the time needed until the numerical values reflect the physiological event.
2. The time between the displayed numerical values exceeding an alarm limit and the alarm indication on the monitor. This delay is the combination of the configured alarm delay time plus the general system delay time.

8.7 PI (Perfusion Index)*

* Only applicable to the EDAN SpO₂ module.

PI is a numeric value indicating perfusion level. It reflects the perfusion level at the monitoring site.

As the measurement of SpO₂ is based on the pulsation caused by the blood flow through the vessel, PI is in relation to the strength of the pulse. Also, you can use PI as a signal quality indicator for the measurement of SpO₂.

PI is indicated by a value ranging from 0 to 10. The bigger the value is, the better the perfusion

and the signal quality will be. The perfusion level and the signal quality are at their maximum when the value reaches 10. When PI is below 2, it indicates the low perfusion and the poor signal quality at the monitoring site; you need to reposition the sensor or find a better site.

The PI value will be displayed on the SpO₂ waveform area.

8.8 SpO₂ Setup

Click on **SpO₂ Setup** in **Main Menu** to enter into **SpO₂ Setup** menu:

- ◆ **Pulse Volume:** Set it to level **0 ~ 5**.
- ◆ **Pitch Tone:** set it to **ON** or **OFF**.
- ◆ **PI:** If it is set to **ON**, the perfusion index will be presented on the main interface. If it is set to **OFF**, the perfusion index is unavailable on screen.

8.9 Alarm

8.9.1 Adjustable Range of Alarm Limits

The range of SpO₂ alarm limit is: 0 ~ 100.

Default SpO₂ alarm limits:

	Max. Upper Limit	Min. Lower Limit	Step
ADU	100	90	1
PED	100	90	1
NEO	95	90	1

The range of PR alarm limit is: 30 ~300.

Default PR alarm limits:

	Max. Upper Limit	Min. Lower Limit	Step
ADU	120	50	1
PED	160	75	1
NEO	200	100	1

8.9.2 Alarm Information and Prompts

When there is no SpO₂ or PR input, it prompts weak signal.

Physiological alarm:

Message	Cause	Alarm Level
SpO ₂ HIGH	SpO ₂ measuring value is above upper alarm limit.	Medium
SpO ₂ LOW	SpO ₂ measuring value is below lower alarm limit.	Medium
PR HIGH	PR measuring value is above upper alarm limit.	Medium
PR LOW	PR measuring value is below lower alarm limit.	Medium
SpO ₂ NO PULSE	Sphygmic signal from the measured position is too weak; the monitor does not detect any sphygmic signal.	High

Technical alarms:

Message	Cause	Alarm Level	What to do
SpO ₂ COMM STOP	SpO ₂ module failure or communication failure	High	Stop using measuring function of SpO ₂ module; notify biomedical engineer or manufacturer's service staff.
SpO ₂ SENSOR OFF	Sensor lose from finger or the monitor failure	Low	Make sure that the monitor and the patient are in correct connection with the cables.
SpO ₂ LOW PERFUSION	The measured signals coming from pulse are too weak.	Low	Reconnect the sensor well, or change the measuring site of body. If the problem persists, please notify biomedical engineer or manufacturer's service staff.
SpO ₂ NO SENSOR	SpO ₂ sensor was not connected well, or the connection is loose.	Low	Make sure the monitor and sensor is well connected, reconnect the sensor.
SpO ₂ NOISY SIGNAL	There is interference with SpO ₂ measurement signals and the waveform is abnormal.	Medium	Check the condition of patient and avoid patient movement; make sure the cable is well connected.

Message	Cause	Alarm Level	What to do
SpO ₂ Interference	Ambient light around the sensor is too strong.	Medium	Reduce interference of the ambient light and avoid sensor's exposure to strong light.

Prompt message:

Message	Cause
Searching pulse	SpO ₂ sensor may be disconnected from the patient or the monitor.
SpO ₂ ALARM OFF	The alarm of SpO ₂ is turned off.

Chapter 9 NIBP Monitoring (Optional)

9.1 Introduction

This monitor uses the oscillometric method for measuring NIBP. It can be used for adult, pediatric and neonatal patients. It is also intended for use with pregnant, including pre-eclamptic patients.

Oscillometric devices measure the amplitude of pressure changes in the occluding cuff as the cuff deflates from above systolic pressure. The amplitude suddenly increases as the pulse breaks through the occlusion in the artery. As the cuff pressure decreases further, the pulsations increase in amplitude, reach a maximum (which approximates to the mean pressure), and then diminish.

The blood pressure measurements determined with this device comply with the American National Standard for Electronic or Automated Sphygmomanometers (ANSI/AAMI/ISO 81060-2:2013) in relation to mean error and standard deviation.

WARNING

1. Do not measure NIBP on patients with sickle-cell disease or any condition where skin damage has occurred or is expected.
 2. Do not measure NIBP on the arm of the same side with a mastectomy.
 3. Use clinical judgment to decide whether to perform frequent unattended blood pressure measurements on patients with severe blood clotting disorders because of the risk of hematoma in the limb fitted with the cuff.
 4. Ensure that the correct setting is selected when performing measurements on children. It may be dangerous for the neonate to use an over pressure level. Not using the neonate mode on a neonatal patient can block the blood flow, potentially causing harm to the patient.
 5. Measuring of blood pressure can temporarily cause malfunctioning of other medical monitoring devices on the same limb.
 6. Before starting a measurement, verify that you have selected a setting appropriate for your patient (adult, pediatric or neonate.)
 7. Do not apply the cuff to a limb that has an intravenous infusion or catheter in place. This could cause tissue damage around the catheter when infusion is slowed or blocked during cuff inflation.
 8. Make sure that the air conduit connecting the blood pressure cuff and the monitor is neither blocked nor tangled.
 9. Do not apply the cuff to a limb where intravascular access or therapy, or an arterio-venous (A-V) shunt is present, otherwise, it may result in injury to the patient.
 10. NIBP readings can be affected by the measurement site, the position of the patient, exercise, or the patient's physiologic conditions.
-

WARNING

11. Continuous cuff pressure due to connection tubing kinking can block the blood flow, and may result in injury to the patient.

NOTE:

- 1 The equipment is suitable for use in the presence of electrosurgery.
- 2 The continuous measuring, automatic measuring and calibration can not be operated on neonatal or pediatric patients.
- 3 Please use the proper type of cuff as recommended in this manual, or the wrong type may lead to injury on the patient, especially when measuring neonatal patients.
- 4 It is suggested that the user should not start NIBP measuring when the low battery displays, or the monitor may be turned off automatically.
- 5 Continuous use of the automatic measuring mode for short interval may lead to the discomfort of patient.
- 6 If you spill liquid onto the equipment or accessories, particularly if there is a chance that it can get inside the tubing or the measurement device, contact your service personnel.
- 7 NIBP measurement can be affected by extremes of temperature, humidity and altitude.

9.2 NIBP Monitoring

To obtain accurate measurements, the following operating steps need to be observed:

1. Ensure the patient position in normal use, including
Comfortably seated (or lie flat on back)
 - Legs uncrossed
 - Feet flat on the floor
 - Back and arm supported
 - Middle of the cuff at the level of the right atrium of the heart
2. Make sure the patient relaxes as much as possible and does not talk during the measurement.
3. Five minutes should elapse before the first reading is taken.

NOTE:

If a NIBP measurement is suspected, repeat the measurement. If you are still uncertain about the reading, use another method to measure the blood pressure.

Measuring procedure:

1. Plug in the sensor and switch on the system.
2. Check whether the patient type is appropriately selected. Enter **Main Menu > Patient Setup** menu and set **Patient Type** to required one.
3. Enter the **NIBP Setup** menu, set the **Unit** of NIBP and select a measurement mode. Select the **Interval** item for **Manual** or set the interval for auto measurement; or select the **Continual**.
4. Apply the blood pressure cuff to the patient's arm or leg following the instructions below.
 - Ensure that the cuff is completely deflated.
 - Apply the appropriate size cuff to the patient, and make sure that the symbol Φ is over the appropriate artery. Ensure that the cuff is not wrapped too tightly around the limb. Excessive tightness may cause discoloration and eventual ischemia of the extremity.

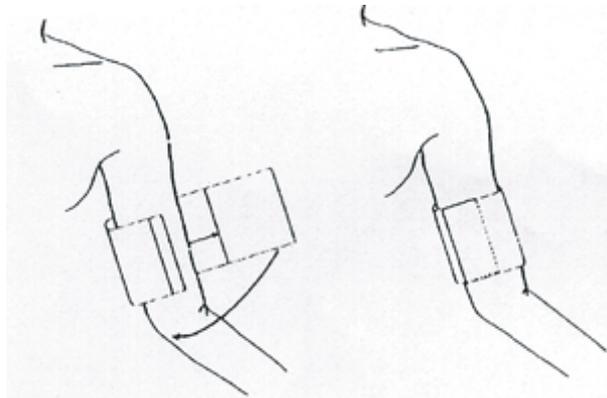


Figure 9-1 Applying Cuff

NOTE:

The width of the cuff is either approximately 40% of the limb circumference or 2/3 of the upper arm length. The inflatable part of the cuff should be long enough to encircle 80-100% of the limb. The wrong size of cuff can cause erroneous readings. If the cuff size is in question, use another cuff with suitable size to avoid errors.

- Make sure that the cuff edge falls within the range of mark $\leftarrow \rightarrow$. If it does not, use a larger or smaller cuff that fits better.
5. Connect the cuff to the air hose. The limb chosen for taking the measurement should be placed at the same level as the patient's heart. If this is not possible you should apply the following corrections to the measured values:
 - If the cuff is placed higher than the heart level, add 0.75 mmHg (0.10 kPa) for each inch of difference.
 - If it is placed lower than the heart level, deduct 0.75 mmHg (0.10 kPa) for each inch of difference.
 6. Press the **NIBP START/STOP** on the front panel to start a measurement. You can also stop

this measurement by pressing this button.

WARNING

Prolonged NIBP measurements in automatic mode may be associated with purpuric, ischemic and neuropathy in the limb wearing the cuff. When monitoring a patient, examine the extremities of the limb frequently for normal color, warmth and sensitivity. If any abnormality is observed, stop the blood pressure measurements.

- To start auto measurement

Access **NIBP Setup** menu and pick the **Interval** item, in which the user may set up the time interval for auto measurement. After that, press the **NIBP START/STOP** on the front panel to start the auto measurement according to the selected time interval.

- To stop auto measuring:

During auto measuring, press the **NIBP START/STOP** on the front panel at any time to stop auto measurement in process.

WARNING

If you repeatedly use **AUTO** measuring in a short term, it may lead to inaccurate readings or endanger patient's life.

- To start a manual measuring:

- Access **NIBP Setup** menu and pick the **Interval** item. Select the **Manual** selection. Then press the **NIBP START/STOP** on the front panel to start a manual measurement.

WARNING

Prolonged NIBP measurements in Auto mode may be associated with purport, ischemia and neuropathy in the limb wearing the cuff. When monitoring a patient, examine the extremities of the limb frequently for normal color, warmth and sensitivity. If any abnormality is observed, stop the blood pressure measurements.

- To start a continuous measuring:

Access the **NIBP Setup** menu and pick the **Continual** item to start a continuous measurement. The continuous measurement will last 5 min.

- To stop measuring:

During measuring press the **NIBP START/STOP** on the front panel at any time to stop measurement.

WARNING

If liquid is inadvertently splashed on the equipment or its accessories, or it may enter the conduit or inside the monitor, contact local Customer Service Center.

NOTE:

If you are in doubt about the accuracy of any reading(s), check the patient's vital signs by an alternative method before checking the functioning of the monitor.

Initial Inflation Pressure

Patient Type	ADU	PED	NEO
Inflation Value	160 mmHg	140 mmHg	100 mmHg

Measurement Limitations

For different patient conditions, the oscillometric measurement has certain limitations. The measurement is in search of regular arterial pressure pulse. In those circumstances when the patient's condition makes it difficult to detect, the measurement becomes unreliable and measuring time increases. The user should be aware that the following conditions could interfere with the measurement, making the measurement unreliable or longer to derive. In some cases, the patient's condition will make a measurement impossible.

- Patient Movement

Measurements will be unreliable or may not be possible if the patient is moving, shivering or having convulsions. These motions may interfere with the detection of the arterial pressure pulses. In addition, the measurement time will be prolonged.

- Cardiac Arrhythmia's

Measurements will be unreliable and may not be possible if the patient's cardiac arrhythmia has caused an irregular heartbeat. The measuring time thus will be prolonged.

- Heart-lung Machine

Measurements will not be possible if the patient is connected to a heart-lung machine.

- Pressure Changes

Measurements will be unreliable and may not be possible if the patient's blood pressure is changing rapidly over the period of time during which the arterial pressure pulses are being analyzed to obtain the measurement.

- Severe Shock

If the patient is in severe shock or hypothermia, measurements will be unreliable since reduced blood flow to the peripheries will cause reduced pulsation of the arteries.

- Heart Rate Extremes

Measurements can not be made at a heart rate of less than 40 bpm and greater than 300 bpm.

9.3 NIBP Setup

In **Main Menu**, open the **NIBP Setup** menu

- **Interval:** Set it to **Manual**, **AVG** or **1/2/3/4/5/10/15/30/60/90/120/240/480 min**. When **Interval** is set to **AVG**, the monitor provides the result by averaging the values obtained from three or five times of NIBP measurement.
- **Unit:** Set the pressure unit to **mmHg** or **KPa**. The setting unit will display on the main interface.
- **Continual:** select it to do NIBP measuring continuously within 5min.

9.4 Alarm

9.4.1 Adjustable Range of Alarm Limits

The adjusting range of NIBP alarm limits:

Adult Mode

SYS 40 mmHg ~270 mmHg

DIA 10 mmHg ~215 mmHg

MAP 20 mmHg ~235 mmHg

Pediatric Mode

SYS 40 mmHg ~230 mmHg

DIA 10 mmHg ~180 mmHg

MAP 20 mmHg ~195 mmHg

Neonatal Mode

SYS 40 mmHg ~ 135 mmHg

DIA 10 mmHg ~ 100 mmHg

MAP 20 mmHg ~ 110 mmHg

Default NIBP alarm limits:

	ADU (mmHg)		PED (mmHg)		NEO (mmHg)	
	Lower Limit	Upper Limit	Lower Limit	Upper Limit	Lower Limit	Upper Limit
SYS	90	160	70	120	40	90
DIA	50	90	40	70	20	60
MAP	60	110	50	90	25	70

PR adjustable range of alarm limits:

	Max. Upper Limit (bpm)	Min. Lower Limit (bpm)	Step (bpm)
PR	240	40	1

Default PR alarm limit:

	Max. Upper Limit (bpm)	Min. Lower Limit (bpm)	Step (bpm)
ADU	120	50	1
PED	160	75	1
NEO	200	100	1

9.4.2 Alarm Information and Prompts

Physiological alarms:

Message	Cause	Alarm Level
SYS HIGH	NIBP SYS measuring value is above upper alarm limit.	Medium
SYS LOW	NIBP SYS measuring value is below lower alarm limit.	Medium
DIA HIGH	NIBP DIA measuring value is above upper alarm limit.	Medium
DIA LOW	NIBP DIA measuring value is below lower alarm limit.	Medium
MAP HIGH	NIBP MAP measuring value is above upper alarm limit.	Medium

Message	Cause	Alarm Level
MAP LOW	NIBP MAP measuring value is below lower alarm limit.	Medium

Technical alarms: (display in the area below the NIBP value):

Message	Cause	Alarm Level	What to do
NIBP COMM STOP	NIBP module failure or communication failure.	High	Stop using measuring function of NIBP module; notify biomedical engineer or manufacturer's service staff.
NIBP INVALID RESET	The hardware pressure is too high	High	Measure again, if failure persists, stop using measuring function of NIBP module and notify biomedical engineer or manufacturer's service staff.
NIBP MODULE ERR	The NIBP module has failure.	High	
LOOSE CUFF	Cuff is no properly wrapped or no cuff exists.	Low	Properly wrap the cuff.
AIR LEAK	Cuff, hose or connector is damaged.	Low	Check and replace the leaking parts, if required, notify biomedical engineer or manufacturer's service staff.
AIR PREESURE ERR	The airway of NIBP has failure.	Low	
NIBP SIGNAL TOO WEAK	Cuff is too loose or patient pulse is too weak.	Low	Use other method to measure blood pressure.
NIBP NOISY SIGNAL	Because of arm motion, signal noise is too large or pulse rate is not regular.	Low	Make sure that the patient under monitoring is motionless.
OVER PRESSURE	Pressure has exceeded the specified upper safety limit.	Low	Measure again, if failure persists, stop using measuring function of NIBP module and notify biomedical engineer or manufacturer's service staff.

Message	Cause	Alarm Level	What to do
NIBP SELFTEST ERR	When the monitor is powered on, NIBP module is detected to fail in calibration.	High	Contact your service personnel.
CUFF TYPE ERR	Cuff type does not comply with the patient type.	Low	Select appropriate cuff type
MEASURE TIMEOUT	Measuring time has exceeded 120s (adult) or 90s (neonatal).	Low	Measure again or use other measuring methods.
INIT PRESSURE TOO HIGH	The initial pressure is too high during measuring.	Low	Measure again, if failure persists, stop using measuring function of NIBP module and notify biomedical engineer or manufacturer's service staff.
PRESSURE RANGE EXCEED	The measured pressure exceeds the limit.	Low	Measure by other method.

Prompt message:

Message	Cause
Press NIBP START	You can start NIBP measuring of continual mode.
Manual measuring...	During manual measuring mode.
Continual measuring...	During continual measuring mode.
Automatic measuring...	During automatic measuring mode.
Measurement over	Measurement over
Calibrating...	During calibrating
Calibration over	Calibration over
Leakage testing...	During leakage test
Leakage test over	Leakage test over
NIBP Resetting...	NIBP module is resetting
NIBP Alarm Off	The alarm of NIBP is turned off.

Chapter 10 TEMP Monitoring (Optional)

10.1 TEMP Monitoring with T2 Module

10.1.1 Introduction

M3A with the T2 module takes a temperature in either Predict or Monitor Mode. In the Predict mode, the monitor measures oral/axillary/rectal TEMP in a short time, calculates and gets the measuring results. In Monitor mode, it can monitor patient for 10 min. The Oral/Axillary sensor and Rectal sensor are of standard configuration.

The monitor can only measure temperature of adult and pediatric patients. If the user measure temperature of neonate patient, the monitor will not display data.

Making a TEMP Measurement

- Select the correct sensor according to the measuring position and patient type.
- Apply the sensor to the patient. You are advised to use a protective rubber cover on sensor.
- Switch on the monitor and ensure the alarm settings (on or off, higher alarm or lower alarm limit) are appropriate for the patient and the type of temperature measurement.
- Select the correct measuring position in menu.

WARNING

- 1 To ensure optimal accuracy, always confirm that the correct mode and alarm limit are selected. Changing the measure position may lead to the change of alarm limit.
 - 2 Verify probe cables fault detection before the beginning of monitoring phase. Unplug the temperature probe cable from the socket, and then the screen will display the error message **TEMP SENSOR OFF** and the audible alarm is activated.
 - 3 Take the TEMP probe and cable carefully. When they are not in use, you should coil up the probe and cable into a loose circle. If the wire inside the cable is tensely pulled, it may cause mechanical damage to the probe and the cable.
 - 4 The calibration of the temperature module is necessary every two years (or as frequently as dictated by your Hospital Procedures Policy). When you need to calibrate the temperature measurement, please contact the manufacturer.
 - 5 Patient actions may interfere with accurate oral temperature readings. Ingesting hot or cold liquids, eating food, chewing gum or mints, brushing teeth, smoking or performing strenuous activity may affect temperature readings for up to 20 min after ending activity.
 - 6 Biting the sensor tip while taking a temperature may result in damage to the sensor.
 - 7 TEMP measurement isn't suitable for use during defibrillation.
-

WARNING

- 8 Do not take an axillary temperature through patient's clothing. Direct probe cover to skin contact is required.
 - 9 Use disposable TEMP sensor covers recommended by EDAN to limit patient cross-contamination. The use of any other probe cover may produce temperature measurement errors or result in inaccurate readings.
 - 10 Make sure you have set the correct measuring position before you start a measurement, or the result will be inaccurate.
 - 11 Do not move the probe during measurement.
 - 12 In monitoring mode, no physiological alarms are available.
-
-

NOTE:

The materials with which the patient or any other person can come into contact conform with the standard of EN ISO 10993-1: 2009.

10.1.2 Measuring Procedure

- 1 Ensure the sensor are well installed. There are icons indicating TEMP measuring position on the main interface. If changing measuring position or measuring mode is necessary, enter menu for setting.
- 2 Take out the sensor from the sensor bracket. After warm-up, it beeps and displays prompt for starting TEMP measuring in information area.
- 3 Load a sensor cover by inserting the sensor into a sensor cover and press the sensor handle firmly. The sensor handle will move slightly to engage the sensor cover.
- 4 Holding the sensor handle with your thumb and two fingers, insert it to the measuring position.

For measuring oral TEMP, place the sensor tip under the patient's tongue on either side of the mouth to reach the rear sublingual pocket. Have the patient close his lips around the sensor.

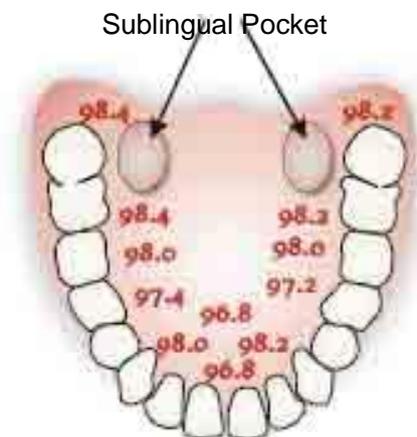


Figure 10-1 Measuring position in mouth

For measuring oral TEMP, do not take an axillary temperature through patient's clothing.

- 5 The monitor enters Predict measuring mode, — — — displays in the TEMP parameter area. After Predict measuring is over, the measuring result displays, and **MEASURE OVER** appears on the interface.
- 6 If the predict measuring is successfully finished, the monitor enters monitor mode after 30s; otherwise the monitor enter monitor mode immediately after the predict measuring. The monitoring state lasts for 10 min, then the monitor enters waiting state. — — — displays in the TEMP parameter area on interface. Put the sensor back into the sensor bracket.
- 7 If necessary, repeat the measurement according to the procedure above.

NOTE:

- 1 After one measurement, the user should put the sensor back to the sensor bracket and then take it out for starting a new measurement.
- 2 The monitor's state can change from the **PREDICT** mode into the **MONITOR** mode, but it can not change from the **MONITOR** mode into the **PREDICT** mode.
3. The reference body site temperature is the same as the temperature of the measuring site.

10.1.3 TEMP Setup

Click on the **TEMP Setup** in the **Main Menu** to display:

- ◆ **Monitor:** when this item is selectable, select it to enter monitor mode.
- ◆ **Position:** you can set this item to **Oral**, **Axillary** or **Recta**. The axillary sensor can be used for measuring oral/axillary temperature, while the rectal sensor for measuring rectal temperature.
- ◆ **TEMP Unit:** Set temperature unit to °C or °F.

10.1.4 Alarm

10.1.4.1 Adjustable Range of Alarm Limits

The range for higher alarm limit and lower alarm limit is as follows:

Patient Type	Measure position	High	Low	Step
ADU	Oral/Axillary/Rectal	+42 °C (+107.6 °F)	+35.5°C (+95.9 °F)	+ 0.1°C
PED	Oral/Axillary/Rectal	+42 °C (+107.6°F)	+35.5°C (+95.9 °F)	+ 0.1°C

10.1.4.2 Alarm Information and Prompts

WARNING

In monitoring mode, no physiological alarms are available.

Physiological alarms:

Message	Cause	Alarm Level
TEMP HIGH	Measuring value of TEMP is above upper alarm limit.	Medium
TEMP LOW	Measuring value of TEMP is below lower alarm limit.	Medium

Technical alarms:

Message	Cause	Alarm Level	What to do
TEMP COMM STOP	TEMP module failure or communication failure.	High	Stop using measuring function of TEMP module; notify biomedical engineer or Manufacturer's service staff.
TEMP EXCCED LIMIT	The TEMP value is beyond the range of +25 °C ~ +45 °C.	Medium	Put the sensor into the sensor bracket, take it out and measure again.
TEMP NO SENSOR	TEMP sensor is not connected to the TEMP module.	Low	Connect the sensor and the monitor well, and measure again.
AMBIENT TEMP HIGH	The Sensor temperature is higher than +40 °C	Low	Put the sensor into the sensor bracket, measure again after the ambient temperature reaches normal value.
AMBIENT TEMP LOW	The Sensor temperature is lower than +10 °C		
TEMP SENSOR ERR	The TEMP sensor cannot work properly.	Medium	Put the sensor into the sensor bracket, take it out and measure again. If the problem persists, stop using measuring function of TEMP module; notify biomedical engineer or Manufacturer's service staff.
TEMP HEATER ERR	Malfunction in the warm-up circuit	Medium	

Message	Cause	Alarm Level	What to do
TEMP SENSOR OFF	After the sensor temperature reaches Predict value, it descends to the value lower than Predict value.	Medium	Reconnect the sensor and make sure that the cable is properly connected.

Prompt:

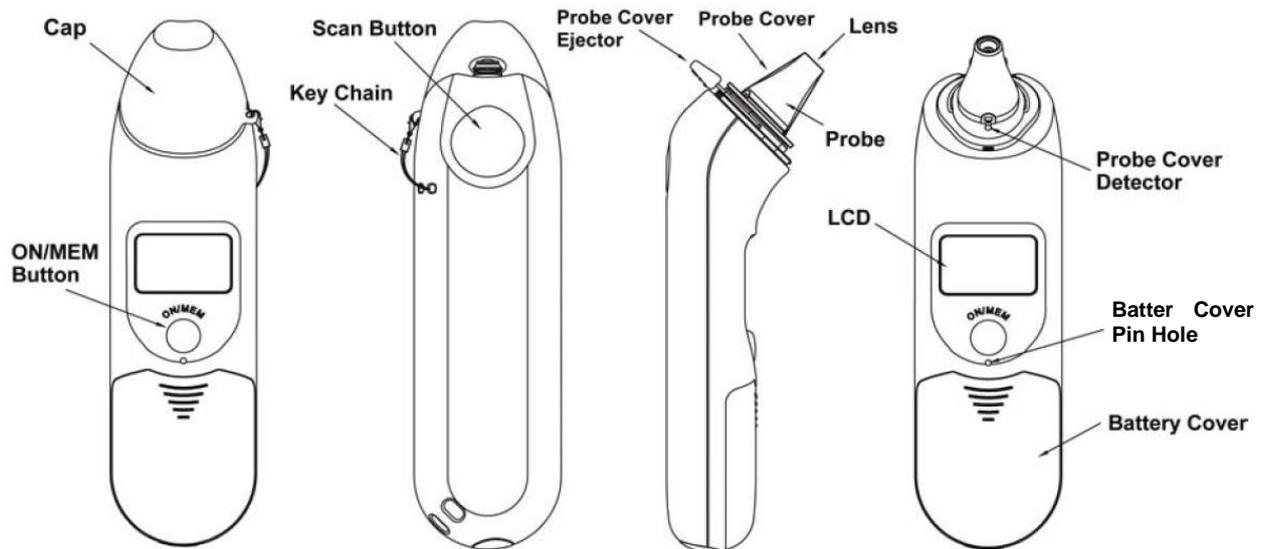
Message	Cause
Ready to TEMP predict	The monitor prompts it after taking the sensor out of the bracket and warm-up is over.
TEMP Predict complete	After the Predict measuring is over, the data and message display on the interface.
TEMP alarm off	The alarm of TEMP is turned off.

10.2 TEMP Monitoring with TH Module

10.2.1 Introduction

M3A with the TH module (Infrared Ear Temperature Module) takes a temperature in the ear.

Diagram of the Infrared Ear Thermometer



WARNING

- 1 Keep the probe covers away from children.
- 2 Do not reuse the disposable probe covers.
- 3 Only use the disposable probe covers supplied or recommended by EDAN. Use of other manufacturer's probe covers, reuse of disposable probe covers or absence of probe covers may produce temperature measurement errors and/or inaccuracies.
- 4 The infrared ear thermometer is not intended for neonatal patients.

CAUTION

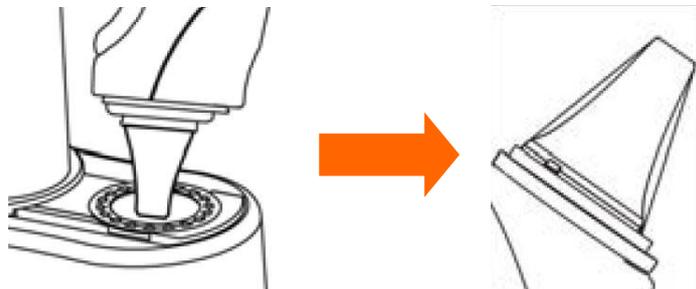
- 1 Keep the probe window clean, dry, and undamaged at times to ensure accurate measurements. To protect the probe window, always keep the thermometer in the storage cover while transporting or when not in use.
- 2 Proper installation of the probe cover ensures accurate measurements.
- 3 Do not autoclave.
- 4 The thermometer is not waterproof. Do not immerse or drip fluids on it. Should this occur, dry the thermometer with warm air. Check for proper operation and accuracy.
- 5 Holding the thermometer too long may cause a higher ambient temperature reading of the probe, which could make the body temperature measurements lower than usual.

CAUTION

- 6 Check whether the thermometer is damaged once it drops. If you cannot make sure of it, send the complete device to your local dealer for recalibration.
- 7 Keep the unit dry and away from any liquids and direct sunlight.
- 8 For more details about using the infrared ear thermometer, refer to the accompanying operating instructions of the thermometer.
- 9 The monitor outfitted with the TH module must not be used together with other electrosurgery equipment, for example, ESU.
- 10 The probe should not be submerged into liquids.
- 11 The calibration of the temperature module is necessary every two years (or as frequently as dictated by your Hospital Procedures Policy). When you need to calibrate the temperature measurement, please contact the manufacturer.

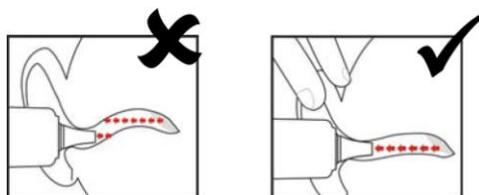
10.2.2 Measuring Procedure

1. Align the center of the probe to the center of the probe cover. Make sure to place the adhesive side of probe cover upward.
2. Insert the probe into the probe cover on the probe cover loader until the probe cover clicks in place.

**NOTE:**

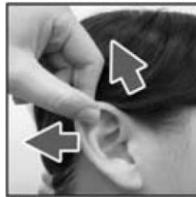
If the probe cover did not install well, the icon  will flash on the LCD of the thermometer, and you cannot take the ear temperature (with four beep sounds heard and without reading on the LCD when measuring).

3. Press ON/MEM button of the thermometer. The icon  will display on the LCD of the thermometer and you will hear two beep sounds.
4. Gently pull the ear back to straighten the ear canal and snugly fit the probe into the ear canal, aiming towards the membrane of the eardrum to obtain an accurate reading.



NOTE:

For children over two-year old and adults: pull the ear straight up and back as shown below:



5. Press the “Scan” button for one second until you hear a long beep sound which signals the end of the measurement, and results will be shown on the display of the monitor.
6. Before starting another measurement, wait until all icons stop flashing and two beep sounds are heard.

WARNING

Replace the probe cover after each use to ensure an accurate reading and avoid cross contamination.

NOTE:

- 1 The thermometer will automatically shut down after one-minute pending to extend battery life.
- 2 The device must stay in stable ambient (room) temperature for 30 minutes before operation.
- 3 Before the measurement, please stay in a stable environment for five minutes and avoid exercise or bath for 30 minutes.
- 4 It is recommended that you measure the same ear for three times. If the three measurements are different, select the highest temperature.
- 5 Remember to compare the measurement result to the regular temperature of the patient.
- 6 There is no gender and age limitation for using infrared ear thermometer.
- 7 The data saved in the thermometer is the last measurement data before the thermometer is powered off.
- 8 Clinical repeatability: 0.12 °C (1~5 years old); 0.10 °C (>5 years old).
- 9 The thermometer converts the ear temperature to display its “oral equivalent” (according to the result of the clinical evaluation)

10.2.3 TEMP Setup

Click on the **TEMP Setup** in the **Main Menu**:

- ◆ **TEMP Unit:** Set temperature unit to °C or °F.

10.2.4 Alarm

10.2.4.1 Adjustable Range of Alarm Limits

The alarm limits are as follows:

Patient Type	Measure position	ALM HI	ALM LO	Step
ADU/PED	Ear	+42 °C (+107.6 °F)	+35.5 °C (+95.9 °F)	+0.1 °C

10.2.4.2 Alarm Information and Prompts

Physiological alarms:

Message	Cause	Alarm Level
TEMP HIGH	Measuring value of TEMP is above upper alarm limit.	Medium
TEMP LOW	Measuring value of TEMP is below lower alarm limit.	Medium

Technical alarms:

Message	Cause	Alarm Level	What to do
TEMP EXCEED LIMIT	The TEMP value is beyond the range of 34 °C --42.2 °C. .	Medium	Check the integrity of the probe cover, make sure it is clean, and take a new measurement.

The infrared ear thermometer will also give error messages on its screen. For details about the error messages, refer to the accompanying operating instructions of the thermometer.

NOTE:

If the infrared ear thermometer frequently signals ERR alarms, the insulated board inside the thermometer housing is malfunctioning or the ambient temperature changes, the monitor will delete the measurement values onscreen to avoid misoperation.

10.2.5 Replacing the Battery

The device is supplied with one lithium cell CR2032x1.

To replacing the battery, follow the procedure:

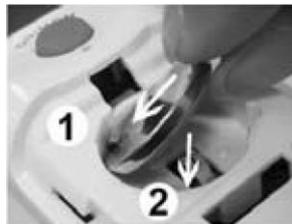
1. Open the battery cover by inserting a pointed object into the battery cover pin hole; meanwhile, use thumb to push battery cover out.



2. Hold the thermometer and flip the battery out with a small screwdriver.



3. Insert the new battery under the metal hook on the left side ① and press the right side ② of the battery down until it clicks in place.



WARNING

- 1 Keep the battery away from children.
 - 2 Ensure the positive (+) side is up and the negative (-) side down.
-

10.2.6 Maintenance

Calibration Mode

To switch to calibration mode, follow the steps below:

- a Press the ON/MEM button to turn the thermometer on. The display of the thermometer shows symbols and functions.
- b Keep pressing the ON/MEM button for five seconds and you will see the “OFF” symbol on the display. Do not release the button until you see a dot onscreen.
- c The thermometer is now in the Calibration Mode and the display is flashing and showing the “CAL” symbol.

NOTE:

It is suggested that a re-test is performed for the device on accuracy after three years. Please send the complete device to the dealers or nearest service address. However, if this device is used according to the operation instructions, periodic re-calibration is not required.

10.3 TEMP Monitoring with F3000 Module

10.3.1 General Information

M3A with the F3000 module measures patient temperatures by oral, axillary or rectal means.

The electromagnetic compatibility of this device has been verified by test according to the EN60601-1-2: 2005 requirements.

The monitor can only measure temperature of adult and pediatric patients. If the user measure temperature of neonate patient, the monitor will not display data.

10.3.2 Safety Information

WARNING

- 1 Do not use this device near flammable anesthetics. Not suitable for use in the presence of flammable anesthetic mixture with air, oxygen or nitrous oxide.
 - 2 Do not use this thermometer without first installing a new probe cover.
 - 3 Use probe covers supplied by the manufacturer with this thermometer only. Use of any other probe cover will result in erroneous temperature readings.
 - 4 The thermometer and probe covers are Non-sterile. Do not use on abraded tissue.
 - 5 To limit cross contamination, use Blue devices for Oral and Axillary temperature taking only.
 - 6 Use RED devices only for RECTAL temperatures.
 - 7 Thoroughly dry all electrical contacts on both probe and thermometer after washing, or device may fail to function properly.
 - 8 For re-calibration, service or integrity checks, refer to a qualified Biomedical Technician or return to the manufacturer.
 - 9 Do not open the F3000 module. No user-serviceable parts inside. Opening of the module may affect calibration and voids warranty.
 - 10 Disposal of used probe covers must be performed in accordance with current medical practices or local regulations regarding disposal of infectious, biological medical waste.
 - 11 The F3000 module is not intended for neonatal patients.
-
-

WARNING

- 12 Cleaning frequency and practices must be consistent with institutional policy for cleaning of non-sterile devices.
 - 13 In monitoring mode, no physiological alarms are available.
-
-

NOTE:

1. Even though this device has been designed to minimize the effects of electromagnetic interference, it does generate radio frequency energy. If not used in accordance with the instructions, the device could cause interference in other equipment operating within its vicinity. If the device is causing interference, the following actions may be taken in an attempt to correct the interference:
 - Re-orient or re-locate the receiving device.
 - Increase the separation between the devices.
 - Consult a customer service representative.
2. The reference body site temperature is the same as the temperature of the measuring site.
3. The calibration of the temperature module is necessary every two years (or as frequently as dictated by your Hospital Procedures Policy). When you need to calibrate the temperature measurement, please contact the manufacturer.

10.3.3 Probe Covers —Applying & Removing

1. Open probe cover box by lifting tab at top corner and pulling to remove top panel.
2. Insert box of probe covers into top of isolation chamber.

NOTE:

To aid infection control, never switch boxes between blue and red isolation chambers. Also, never switch probes between blue and red isolation chambers. Keep like colors together.

3. Remove probe from the probe well. This automatically turns on the thermometer.
4. To help remind the user to apply or remove a probe cover, a probe icon with flashing probe cover will be displayed when the probe is withdrawn from the probe well and following a completed temperature measurement.
5. Insert the probe end into a cover in the box. Push the handle firmly until you feel the cover “snap” into place.
6. Take appropriate temperature measurement (oral, axillary or rectal).
7. Eject the used cover into bio-waste container by pressing top button.
8. Remove, discard and replace box when empty.

10.3.4 Changing Isolation Chambers and Probes

NOTE:

- 1 For aiding in infection control, use only the Blue probe and Blue isolation chamber for Oral and Axillary temperature taking. The Red probe and Red isolation chamber must only be used for Rectal temperature taking.
- 2 Do not attach a Red probe to a Blue isolation chamber or vice-versa.
1. To remove or replace any isolation chamber/probe assembly, grasp the isolation chamber from each side as shown.
2. Squeeze inward releasing the snaps and slide the isolation chamber up to pull off.
3. To replace, align probe well finger with opening in the top of the unit.
4. Slide the isolation chamber down until the side snaps “click” into place.
5. The probe is connected to the thermometer automatically.
6. To change probes, remove the isolation chamber as described previously.
7. Grasp the sides of the L-shaped connector piece with one hand and then using other hand pull backward on the latch holding the end of the L-shaped connector.
8. Once free of the latch, slide the L-shaped connector out of isolation chamber.
9. To replace, properly align the top of the L-shaped connector to the slot on the back of the isolation chamber.
10. Then slide the connector up into the slot pressing firmly on the bottom of the connector until it “clicks” into place.

10.3.5 Measuring Mode

Predictive Mode

When **Mode** is set to **Predict**, the monitor operates in Predictive Mode to provide fast and accurate temperature measurements.

Quick Predictive Mode

When **Mode** is set to **Quick Predict**, the monitor operates in Quick Predictive Mode which is an oral predictive measurement mode intended for situations where fast temperature measurements are desired.

Quick Predictive Mode allows clinicians to rapidly identify patients with “normal” body temperatures. If the patient temperature is outside of the “normal” range, the monitor will automatically switch into its standard predictive mode to provide a more accurate reading.

Quick Predictive Mode is not available when in Cold Mode.

Monitoring Mode

When **Mode** is set to **Monitor**, the monitor will perform continual temperature measurement for a maximum of 5 minutes.

Besides, in the following instances, the monitor will automatically switch to Monitoring Mode and perform temperature measurement for a maximum of 5 minutes until the temperature stabilizes:

1. When the monitor operates in Predictive Mode, no measurement site is detected or the temperature does not stabilize.
2. When the monitor operates in Predictive Mode or Quick Predictive Mode, the ambient temperature is greater than 35 °C (95 °F).

Cold Mode

Cold Mode is provided for use in applications where body temperatures may be lower than “normal”, such as for patients recently out of surgery.

The accuracy and measurement time of Cold Mode measurements are equivalent to standard prediction measurements at the respective body sites.

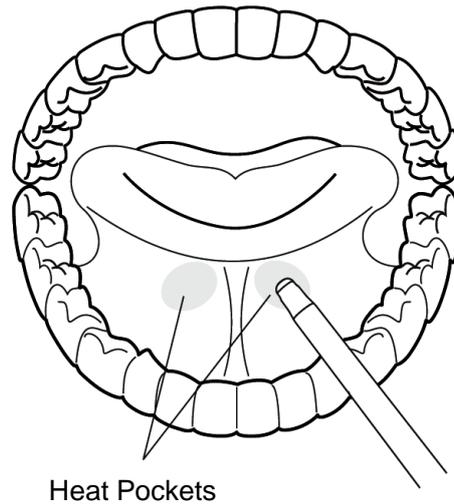
10.3.6 Measuring Procedure

Oral and Axillary Temperature Taking

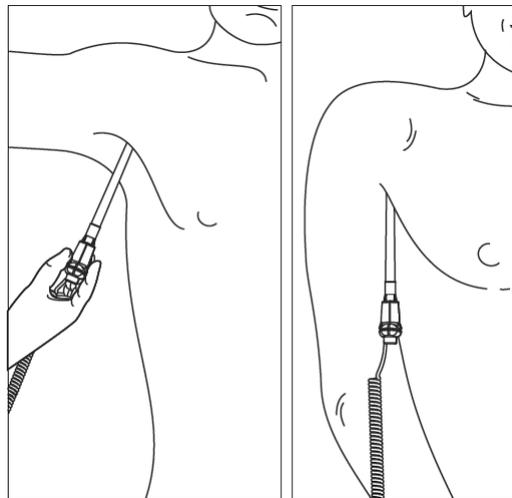
1. Make certain that the Blue isolation chamber /probe unit is attached.
2. Withdraw probe and apply a probe cover. The thermometer turns on automatically a beep will be heard when the probe completes warm-up.
3. For Oral temperatures, insert the probe tip deep into the sublingual pocket next to the frenulum linguae, (vertical fold of tissue in middle of tongue), on one side or the other, toward the back of the mouth.

NOTE:

Accurate body temperature readings can only be obtained in one of these two “heat pocket” locations as shown. Temperatures taken in other mouth locations will result in inaccurate body temperature readings.



4. Patient's mouth must be CLOSED.
5. Securely hold the probe in place until the temperature is displayed.
6. For Axillary temperatures, have the patient raise the arm, then place the probe tip in the axilla. Press gently to assure good contact. For the most accurate temperature the probe tip should be placed directly against the patient's skin.
7. Have the patient then lower the arm and remain as still as possible. Hold the probe parallel to the arm as shown.



8. If three short beeps are heard, it means the unit switched to Monitoring Mode for this temperature only.
9. Two beeps are sounded when measurement is complete and the final temperature is displayed.
10. Eject the used cover into a bio-waste container by pushing top button.

Rectal Temperature Taking

1. Make certain that the Red isolation chamber/probe unit is attached.
2. Withdraw the probe and apply a probe cover. Thermometer turns on automatically a beep

will be heard when the probe completes warm-up.

3. Apply lubrication if desired.
4. Insert the probe into the patient's rectum. To ensure proper tissue contact, angle the probe slightly after insertion.*
5. Depth of insertion is recommended at 1/2" to 3/4" (12 mm - 19 mm) for adults and 1/4" to 1/2" (6 mm - 13 mm) for children.
6. If three short beeps are heard, it means the unit switched to Monitoring Mode for this temperature only.
7. Two beeps are sounded when measurement is complete and the final temperature is displayed.
8. Eject the used cover into a bio-waste container by pushing top button.

NOTE:

- 1 Probe movement during a measurement can affect the thermometer's ability to measure the site temperature and may lengthen the time required to obtain a reading.
- 2 If a beep is not heard 10 seconds after withdrawing the probe from the probe well and starting temperature measurement in Predictive Mode or Quick Predictive Mode, check the physical connection of the F3000 module.

10.3.7 TEMP Setup for F3000 Module

Click **TEMP Setup** in the **Main Menu**, and the following settings are available:

Mode: Set the measuring mode to **Predict**, **Quick Predict** or **Monitor**.

Position: Set the measuring position to **Oral**, **Axillary** or **Rectal**.

Cold Mode: Activate /deactivate the cold mode by setting it to **ON** /**OFF**.

TEMP Unit: Set temperature unit to **°C** or **°F**.

NOTE:

- 1 The **Quick Predict** mode is for oral measurement only.
- 2 The **Quick Predict** mode is unavailable when **Cold Mode** is set to **ON**.
- 3 Make sure all settings of TEMP Setup are properly set up every time before you withdraw the probe from the probe well. If you modify the settings immediately a measurement is completed, the new settings will be effective for the next measurement.

10.3.8 Alarm

10.3.8.1 Adjustable Range of Alarm Limits

Patient Type	Measure position	ALM HI	ALM LO	Step
ADU/PED	Oral/Axillary/Rectal	+43 °C (39 °C by default)	+33 °C (36 °C by default)	0.1 °C

10.3.8.2 Alarm Information and Prompts

WARNING

In monitoring mode, no physiological alarms are available.

Physiological alarms:

Message	Cause	Alarm Level
TEMP HIGH	Measuring value of TEMP is above the upper alarm limit.	Medium
TEMP LOW	Measuring value of TEMP is below the lower alarm limit.	Medium

Technical alarms:

Message	Cause	Alarm Level	What to do
Temp COMM STOP	TEMP module failure or communication failure.	High	Stop using measuring function of TEMP module; notify biomedical engineer or Manufacturer's service staff.
Temp exceed limit	The TEMP value is out of the range of +30 °C ~ +43 °C.	Medium	Put the probe into the probe well; take it out and measure again.
No TEMP SENSOR	Probe configuration (or no probe connected) error.	Low	Well connect the probe and the monitor, and measure again.
TEMP SENSOR ERR	Incorrect sensor type or incorrect measure sites	Medium	Use the correct type of sensor; choose the correct measure site.

Message	Cause	Alarm Level	What to do
Temp Error P06	Unable to pre-heat probe tip.	Low	Stop using measuring function of TEMP module; notify biomedical engineer or Manufacturer's service staff. NOTE: Measure readings displayed on the screen are unreliable when the monitor indicates Temp Error P06.
Temp Error E01	System error during synchronization.	Medium	Stop using measuring function of TEMP module; notify biomedical engineer or Manufacturer's service staff.
Temp Error E02	System error during patient thermistor calibration.	Medium	
Temp Error E03	System error during heater thermistor calibration.	Medium	
Temp Error E04	System timing error.	Medium	
Heater error	Heater error.	Medium	
Temp Error P02	Direct Mode patient thermistor unstable or out of range.	Low	
Temp Error P03	Direct Mode heater thermistor unstable or out of range.	Low	
Temp Error P04	Predict Mode patient thermistor unstable or out of range.	Low	
Temp Error P05	Predict Mode heater thermistor unstable or out of range.	Low	

Prompts:

Message	Cause
Ready to TEMP predict	The monitor prompts it after the probe is taken out of the probe well and preheating is completed.
Prediction complete	Prediction measurement is completed.
TEMP Monitor	The monitor operates in Monitor Mode.

Chapter 11 Other Functions

11.1 Nurse Call

The monitor provides dedicated nurse call port which is connected to nurse call system through the nurse call cable to perform the nurse call function.

NOTE:

Before using the function of nurse call, check if it is functioning normally.

11.2 Network

The monitor can be connected with PC through network port. Our company arranges the qualified engineers to install and set the wired network for the user and test the corresponding performance.

11.3 Central Monitoring System

The monitor can be connected to the central monitoring system. Through the network:

1. The monitor sends patient information, real-time monitoring or measurement data to the central monitoring system.
2. The real-time monitoring information is displayed on the central monitoring system as the same to the monitor, and the central monitoring system can perform some bilateral control. For example: changing patient information, receiving patient, discharging patient and so forth.
3. The alarm information of bed side monitor is displayed on the central monitoring system. For example: audio alarm paused, audio alarm off and physiological alarm status and so on.

For detailed information, please refer to *MFM-CMS Central Monitoring System User Manual*.

NOTE:

- 1 Make sure the network connection between the monitor and the central monitoring system is in good condition when the time synchronization function on the monitor is active.
- 2 The time synchronization function might not be available to all software versions of MFM-CMS. Consult our technical service department or your local distributor for more information.

Chapter 12 Accessories and Ordering Information

You can order accessories from EDAN supplies at www.edan.com.cn or consult your local Edan representative for details.

WARNING

- 1 Never reuse disposable transducers, sensors, accessories and their casing that are intended for single use; or only use them on a single patient. Reuse may compromise device functionality and system performance and cause a potential hazard.
- 2 Use only EDAN-approved accessories. Using non-EDAN-approved accessories may compromise device functionality and system performance and cause a potential hazard. It is not recommended to use accessories supplied by EDAN with patient monitors by other manufacturers.
- 3 Do not use a sterilized accessory if its casing is damaged.

NOTE:

Transducers and sensors have a limited shelf life. Refer to the package labeling.

The following cables may not all be available in all countries. Please check availability with your local EDAN supplier.

The following accessories are recommended when using this monitor.

EDAN SpO₂	
02.01.210119	LEMO SH1 Adult reusable, SpO ₂ Sensor
02.01.210120	EDAN SH1 Adult Reusable SpO ₂ Sensor
02.01.110492	EDAN SH3 Neonate Warp SpO ₂ Sensor
02.01.210122	EDAN SH4 Adult Silicone Soft-tip SpO ₂ Sensor
02.01.210121	EDAN SH5 pediatric Silicone Soft-tip SpO ₂ Sensor
01.13.210001	SpO ₂ Extension cable
01.57.471238	EDAN Neonate Single-Patient SpO ₂ sensor SHD-N
01.57.471237	EDAN Infant Single-Patient SpO ₂ sensor SHD-I
01.57.471236	EDAN Pediatrics Single-Patient SpO ₂ sensor SHD-P
01.57.471235	EDAN Adult Single-Patient SpO ₂ sensor SHD-A

NIBP	
01.57.471326	Reusable blood pressure cuff, infant, E5
01.57.471327	Reusable blood pressure cuff, small, child, E6
01.57.471328	Reusable blood pressure cuff, child, E7
01.57.471329	Reusable blood pressure cuff, small, adult, E8
01.57.471330	Reusable blood pressure cuff, adult, E9
01.57.471331	Reusable blood pressure cuff, large, adult, E10
01.59.036118	NIBP Tube for Adult Pediatric, 3m, Grey
01.57.471442	NIBP Cuff, E7, Child, reusable, (16-21.5) cm
01.57.471443	NIBP Cuff, E8, Small adult, reusable, (20.5-28) cm
01.57.471444	NIBP Cuff, E9, Adult, reusable, (27-35) cm
01.57.471005	NIBP Tube, 3m
01.57.471291	NIBP Tube, 3m
01.57.471303	NIBP Tube, 3m
01.57.471021	Disposable connecting Tube for Neonatal Cuff, single use
TEMP (For T2 Module)	
02.04.110140	Oral /axillary probe
02.04.110139	Rectal probe
01.57.110159	Probe covers
TEMP (For TH Module)	
01.13.036415	TH module communication wire
01.57.208057	Infrared Ear Thermometer
02.08.208058	Probe covers for TH module (200 pieces/ package)

02.08.208059	Probe cover loader for TH module (with 40 pieces probe cover)
TEMP (For F3000 Module)	
01.57.471312	Filac 3000 Oral Probe 4ft
01.57.471313	Filac 3000 Oral Probe 9ft
01.22.066159	Filac 3000 Oral Isolation Chamber
01.57.471314	Filac 3000 Rectal Probe 4ft
01.57.471315	Filac 3000 Rectal Probe 9ft
01.22.066160	Filac 3000 Rectal Isolation Chamber
01.57.471316	Filac 3000 Probe Covers
Others	
01.57.78035	Printing Paper
03.28.101950	Trolley
01.13.36014	Power Cable(IEC Standard) ,1.8 m
01.13.036106	Power cord(USA),1.8 m
01.21.064167	Rechargeable Lithium-Ion Battery/ TWSLB-008 (14.8V, 4400 mAh)
01.21.064168	Rechargeable Lithium-Ion Battery/ TWSLB-009 (14.8V, 2200 mAh)
01.21.064142	Rechargeable Lithium-Ion Battery/ TWSLB-002 (14.8V, 2500 mAh)
01.21.064143	Rechargeable Lithium-Ion Battery/ TWSLB-003 (14.8V,5000 mAh)
01.13.01950	Power cord(3C),3 m
01.13.114214	Ground Cable
01.23.068003	USB barcode scanner (Cipher LAB 1000U, USB port, contact, CCD scan)
01.18.052267	Planar barcode scanner (Z-3152SR(U), DC 5 V, 280 mA, USB port)

Chapter 13 Warranty and Service

13.1 Warranty

EDAN warrants that EDAN's products meet the labeled specifications of the products and will be free from defects in materials and workmanship that occur within warranty period.

The warranty is void in cases of:

- a) damage caused by mishandling during shipping.
- b) subsequent damage caused by improper use or maintenance.
- c) damage caused by alteration or repair by anyone not authorized by EDAN.
- d) damage caused by accidents.
- e) replacement or removal of serial number label and manufacture label.

If a product covered by this warranty is determined to be defective because of defective materials, components, or workmanship, and the warranty claim is made within the warranty period, EDAN will, at its discretion, repair or replace the defective part(s) free of charge. EDAN will not provide a substitute product for use when the defective product is being repaired.

13.2 Contact Information

If you have any question about maintenance, technical specifications or malfunctions of devices, contact your local distributor.

Alternatively, you can send an email to EDAN service department at: support@edan.com.cn.

Appendix I Specifications

A1.1 Classification

Anti-electroshock type	Class I equipment and internally powered equipment
Anti-electroshock degree	SpO ₂ , NIBP: BF TEMP: CF (T2 module) BF (TH module, F3000 module)
Ingress Protection	IPX1 With T2, TH or F3000 TEMP module: Ordinary equipment (Sealed equipment without liquid proof)
Working system	Continuous operation equipment
Compliant with Safety Standards	IEC 60601-1: 2005+A1:2012; EN 60601-1: 2006+A1: 2013;IEC 60601-1-2:2007; EN 60601-1-2: 2007;IEC 80601-2-30; ISO 80601-2-61;ISO 80601-2-56;IEC 60601-2-49

A1.2 Specifications

NOTE:

The performance of the equipment with ☆ mark is determined to be essential performance.

A1.2.1 Size and Weight

Size	(174±2) mm(W) × (235±2) mm(H) × (189±2) mm (D)
Weight	≤3 kg (without battery)

A1.2.2 Environment

The monitor may not meet the performance specifications given here if stored or used outside the specified temperature and humidity ranges.

When the monitor and related products have differing environmental specifications, the effective range for the combined products is that range which is common to the specifications for all products.

Temperature	
Working	0 °C ~ +40 °C(32 °F ~104 °F)
	With TEMP: +10 °C ~ +40 °C(50°F ~104°F)
Transport and Storage	-20 °C ~ +55 °C(-4°F ~131°F)
	With TH module: -20 °C ~ +50 °C(-4°F ~122°F)
Humidity	
Working	15% RH~ 95% RH (non- condensing)
Transport and Storage	15% RH~ 95% RH(non- condensing)
Altitude	
Working	86 kPa ~ 106 kPa
Transport and Storage	70 kPa ~ 106 kPa
Power Supply	Voltage: 100 V~240 V ~ Frequency: 50 Hz/60 Hz Pmax: 70 VA FUSE: T2.0 AH250 VP

A1.2.3 Display

Multicolor LCD	Resolution: 320×240, adjustable brightness
Messages	1 power supply indicator LED (Green) 1 power on indicator LED (Green) 1 alarm indicator LED (Cyan/Yellow/ Red) 1 alarm silence indicator LED (Yellow) 1 charge indicator LED (Yellow) 1 NIBP working status indicator LED (Backlight) 3 indicating modes correspond to alarm mode

A1.2.4 Battery

Quantity	1
Type	Li battery

Capacitance	Standard: 2200 mAh/4400 mAh; Optional: 2500 mAh/5000 mAh
Typical Working Period	2200 mAh: 8.5 h; 2500 mAh: 9 h 4400 mAh: 17 h; 5000 mAh: 18 h (With a new fully charged battery, at +25 °C, continuous SpO ₂ measuring, NIBP automatic measuring mode with the operating interval of 15 minutes)
Maximum Rechargeable Period	2200 mAh: 3 h; 2500 mAh: 4 h 4400 mAh: 5.5 h; 5000 mAh: 6 h (Monitor is on or in standby mode.)

A1.2.5 Recorder

Record width	48 mm
Paper speed	25 mm/s
Recording types	Real-time data recording
	Trend graph review recording
	Trend table review recording
	Alarm list recording

A1.2.6 Data Storage

Trend data storage	12, 000 groups data
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A1.2.7 NIBP (Optional)

Mode	Manual, Auto, Continuous
Measuring interval in AUTO mode (unit: minute)	1/2/3/4/5/10/15/30/60/90/120/240/480
Continuous	5 min, interval is 5 s
Measuring type	Systolic Pressure, Diastolic Pressure, Mean Pressure, Pulse Rate
☆Measuring range	

ADU mode	SYS 40 mmHg ~270 mmHg
	DIA 10 mmHg ~ 215 mmHg
	MAP 20 mmHg ~235 mmHg
PED mode	SYS 40 mmHg ~230 mmHg
	DIA 10 mmHg ~180 mmHg
	MAP 20 mmHg ~195 mmHg
NEO mode	SYS 40 mmHg ~ 135 mmHg
	DIA 10 mmHg ~100 mmHg
	MAP 20 mmHg ~110 mmHg
Alarm type	SYS, DIA, MAP, PR
Cuff Pressure measuring range	0 mmHg ~300 mmHg
Pressure resolution	1 mmHg
☆Maximum mean error	± 5 mmHg
☆Maximum standard deviation	8 mmHg
Maximum measuring time of single measurement	ADU/PED 120 s
	NEO 90 s
Typical measuring period	20 s ~ 35 s (depend on HR/motion disturbance)
Overpressure protection	
ADU	(297 ±3) mmHg
PED	(245 ±3) mmHg
NEO	(147 ±3) mmHg
PR	
☆Measuring range	40 bpm ~ 240 bpm
☆Accuracy	±3 bpm or 3.5%, whichever is greater

A1.2.8 SpO₂ (Optional)

☆Measuring Range	0% ~100%
☆Adjustable Range of Alarm Limits	0% ~100%
Resolution	1%

Data update period	1s
☆Accuracy	
ADU & PED	±2% (70% - 100% SpO ₂) Undefined (0% - 69% SpO ₂)
NEO	±3% (70% - 100% SpO ₂) Undefined (0% - 69% SpO ₂)
Pulse Rate	
Measuring Range	25 bpm - 300 bpm
☆Adjustable Range of Alarm Limits	30 bpm - 300 bpm
Resolution	1 bpm
Accuracy	± 2 bpm
Perfusion Index	
Measuring Range	0-10. It displays 0 for invalid PI value.
Resolution	1
Sensor	
Red light	(660±3) nm
Infrared light	(905±10) nm
Emitted light energy	< 15 mW

NOTE:

The information about wavelength range can be especially useful to clinicians (for instance, when photodynamic therapy is performed).

A1.2.9 TEMP (Optional)**T2 Module:**

☆Measuring range	Monitor mode: 25 °C ~ 45 °C Predict mode: 35.5 °C~ 42 °C
Working temperature	10 °C ~ 40 °C
Sensor type	Oral /axillary /rectal
☆Adjustable Range of Alarm Limits	35.5 °C ~ 42 °C

Resolution	0.1 °C
☆Accuracy	Monitor mode: ± 0.1 °C (25 °C ~ 45 °C) (not including transducer)
Response time	< 60 s
Update time	1 s ~ 2 s
Warm-up time	<10 s
Time for predicting	<30 s
Calibration	Self-test interval: ≤ 5 minutes
Measuring Mode	Direct Mode/ Adjusted Mode
Transient Response Time	≤ 30 s
Clinical Bias	(-0.2 to -0.4) °C
Limits of Agreement	0.49
Repeatability	0.14 °C

NOTE:

The direct mode refers to monitor mode, while adjusted mode refers to predict mode.

TH Module:

☆Measuring range	34 °C ~ 42.2 °C
Working temperature	10 °C ~ 40 °C
☆Adjustable Range of Alarm Limits	35.5 °C~ 42 °C
Resolution	0.1 °C
☆Clinical Accuracy	± 0.2 °C (0.4 ° F)(35.5 °C ~42 °C) (95 ° F -107.6 ° F) ± 0.3 °C (0.5 ° F)(out of the range mentioned above)
☆Laboratory Accuracy	± 0.2 °C
Response time	1 s
Measuring Mode	Adjusted Mode

F3000 Module:

☆Measuring range	30 °C~43 °C
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Prediction measurement range	35 °C~43 °C
Cold mode prediction measurement range	33 °C~ 43 °C
Working temperature	10 °C ~ 40 °C
Sensor type	Oral /axillary /rectal
☆Adjustable Range of Alarm Limits	33 °C ~ 43 °C
Resolution	0.1 °C
Measuring Mode	Direct Mode /Adjusted Mode
Clinical Bias	(-0.2 to -0.4) °C
Limits of Agreement	0.49
Repeatability	0.14 °C
Transient Response Time	≤30 s
☆Accuracy	Monitoring Mode and Predictive Mode: ±0.1 °C Quick Predictive Mode: ±0.3 °C
Typical measurement time (after insertion into measurement site)	Oral (Quick Predictive Mode): (3~5) seconds (non-fever temps); (8~10) seconds (fever temps)
	Oral (Predictive Mode): (6~10) seconds
	Axillary: (8~12) seconds
	Rectal: (10~14) seconds
	Monitoring Mode (all sites): (60~120) seconds

NOTE:

The direct mode refers to monitor mode, while adjusted mode refers to predictive mode and quick predictive mode.

Appendix II EMC Information - Guidance and Manufacturer's Declaration

A2.1 Electromagnetic Emissions

Guidance and manufacture's declaration-electromagnetic emission		
The M3A is intended for use in the electromagnetic environment specified below; the customer or the user of the M3A should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The M3A uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The M3A is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies building used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC61000-3-3	Complies	

A2.2 Electromagnetic Immunity

Guidance and manufacture's declaration – electromagnetic immunity			
The M3A is intended for use in the electromagnetic environment specified below. The customer or the user of M3A should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment -guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air;	±6 kV contact ±8 kV air With TH/F3000 module: ±2 kV contact ±4kV air.	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.

Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines;	± 2 kV for power supply lines; With TH/F3000 module: ± 1 kV for power supply lines.	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line to line ± 2 kV line to ground	± 1 kV line to line ± 2 kV line to ground	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60Hz) magnetic field IEC61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the M3A requires continued operation during power mains interruptions, it is recommended that the M3A be powered from an uninterruptible power supply or a battery.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

NOTE:

1. High level ESD may cause communication failure between TH module/F3000 module and the device.
2. High level Electrical fast transient/burst may cause communication failure between TH module and the device.

A2.3 Electromagnetic Immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The M3A is intended for use in the electromagnetic environment specified below. The customer or the user of M3A should assure that it is used in such an environment.			
Immunity test	IEC/EN 60601 test level	Compliance level	Electromagnetic environment -guidance
Conducted RF IEC/EN 61000-4-6	3 Vrms 150 kHz to 80 MHz	3Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the M3A, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ 150 kHz to 80 MHz
Radiated RF IEC/EN 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless)			

telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the M3A is used exceeds the applicable RF compliance level above, the M3A should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the M3A.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

A2.4 Recommended Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and the M3A			
The M3A is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the M3A can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the M3A as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

P/N: 01.54.112593

MPN: 01.54.112593017

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